Determination of the Generally Recognized As Safe (GRAS) Status of Resistant Dextrin

Prepared for:
Anderson Global Group (AGG)

Prepared by:
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GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF RESISTANT DEXTRIN

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List of Abbreviations

AGG = Anderson Global Group
AOAC = Association of Official Analytical Communities
BAM= Bacteriological Analytical Manual
bw = body weight
CAS = Chemical Abstract Service
CFR= Code of Federal Regulations
Ch=chapter
cGMP = current good manufacturing practice
COA = certificate of analysis
DAM = daunomycin
DP = degree of polymerization
DRV = Daily Reference Value
DTC = dithiocarbamate
EDI = estimated daily intake
FD&C = Federal Food, Drug, and Cosmetic
FDA = Food and Drug Administration
GRAS = Generally Recognized As Safe
ICP MS= Inductively coupled plasma mass spectrometry.
IOM = Institute of Medicine
LD_{50} = lethal dose
MMS = methyl methanesulfonate
Mn = number average molecular weight (meaning the lowest molecular weight portion of the sample)
Mw = weight average molecular weight
NHANES = National Health and Nutrition Examination Survey
NOAEL = No Observed Adverse Effect Level
NPD = 4-nitro-o-phenylenediamine
OECD = Organization for Economic Co-operation and Development
SCFA = short-chain fatty acid
SD = Sprague-Dawley
U.S. = United States
U.S.C. = United States Code
UL = Tolerable Upper Intake Level
1,8-DT = 1,8-dihydroxyanthraquinone (also known as dantron)
2-AA = 2-aminoanthracene
2-AF = 2-aminofluorene

PART 1. SIGNED STATEMENTS AND CERTIFICATION

1.A. GRAS Notice Submission

Pursuant to 21 Code of Federal Regulations (CFR) Part 170, subpart E, Anderson Global Group (AGG) submits a Generally Recognized as Safe (GRAS) notice for its resistant dextrin (FiberSMART®-tapioca) through its agent, AceOne RS, Inc. (formerly NutraSource, Inc.).

1.B. Name and Address of Notifier

Contact person: Steve Prancevic
Company name: Anderson Global Group (AGG)
Address: 2030 Main Street, Irvine, CA 92614
Telephone number: (949) 502-4770
E-mail Address: stevep@andersonglobalgroup.com

1.C. Names of Notified Substance

Common name is resistant dextrin.
Synonyms include resistant maltodextrin or indigestible dextrin, resistant dextrin-tapioca, resistant dextrin (tapioca), tapioca fiber, or soluble tapioca fiber.
Trade name is FiberSMART® or FiberSMART®-tapioca.

1.D. Intended Conditions of Use

1.D.1. Foods in Which the Substance is to be Used

The intended use levels will be 1.2 to 10 g/serving in selected conventional foods. The intended use is similar to those described in GRN 436 for most of the food categories except a newly added category of nutrition bar at 10 g/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; (16) dry beverage powder; and (17) nutrition bars. AGG does not intend to use resistant dextrin as a component of infant formula or in foods under the United States Department of Agriculture (USDA)'s jurisdiction, such as meat, poultry, or egg products.

1.D.2. Levels of Use in Such Foods

Table 1 summarizes the intended use levels. The use levels are very similar to those described in GRN 436 for most of the food categories except a few items listed below:

1) In GRN 436, it was indicated that 9 g resistant dextrin was in dry instant coffee powder products, whose serving size is 2.4 g (corresponding food codes; NHANES food codes-92191000, 92191100, 92191200, and 92191300). AGG intends to use 1.2 g resistant dextrin in these dry instant coffee powders.

2) GRN 436 also assumed the use of 3 g resistant dextrin in dietetic mint, whose serving size is 2 g (corresponding food code; NHANES food code, 91770050). AGG intends to use 1.2 g resistant dextrin in this mint product.

3) In this GRAS determination, the new food category, nutrition bars, has been added at 10 g/serving or 20% (w/w).

Table 1. Intended Use and Maximum Use Levels of Resistant Dextrin % (w/w)

Food category	Maximum use level, g/serving	RACC[a], g
Baked goods	3	15-140
Beverages liquid non-dairy	3	36-360
Cereals and granola bars	6	15-60 (dry); 234-256 (cooked)
Nutrition bars	10	50
Condiments and dressings	3	5-60
Confections	1.2-3	15-30 except dietetic mint (2 g/RACC)
Dairy beverages	3	15-250
Dairy non-beverages	3	5-170
Dry beverage powder	1.2-9	1.4 -360[b]
Frozen desserts	3	85-213
Gravies and sauces	3	30-125
Meal replacements	3	20-248
Pasta and grain products	3	91-248
Prepared meals and soups	3	7-254
Processed fruits	3	40-140
Shelf-stable desserts	3	113.5-133.5
Snacks and crackers	3	30-232

[a]Based on the Reference Amounts Customarily Consumed (RACC) Per Eating Occasion (21 CFR §101.12; https://www.ecfr.gov/on/2020-12-31/title-21/chapter-I/subchapter-B/part-101).
[b]Some of these food codes designate that the beverage is reconstituted with RACC values around 360 g for some types of drinks and around 240 g for some other types of drinks. Some of the food codes are just the powder and are not reconstituted.

1.D.3. Purpose for Which the Substance is Used

The substance will be used as a food ingredient.

1.D.4. Description of the Population Expected to Consume the Substance

The population expected to consume the substance consists of members of the general population who consume at least one of the products described above.

1.E. Basis for the GRAS Determination: Through scientific procedures.

1.F. Premarket Exempt Status

Since AGG has determined that the intended use of its resistant dextrin, FiberSMART®-tapioca, is GRAS, such use is not subject to premarket approval requirements under the Federal Food, Drug, and Cosmetic Act.

1.G. Availability of Information

The data and information that serve as the basis for this GRAS determination will be sent to the Food and Drug Administration (FDA) upon request, or are available for the FDA's review and copying at reasonable times at the office of AceOne RS, Inc.

1.H. Availability of Freedom of Information Act Exemption

None of the data and information in Parts 2 through 7 of this GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 United States Code (U.S.C.) §552.

1.I. Certification

To the best of our knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the intended use of the substance.

Steve A Prancevic

_____ December 20, 2021

Name: Steve Prancevic Date

Title: Vice President

Please address correspondence to

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1.J. Food Safety and Inspection Service/USDA Statement

Resistant Dextrin is not intended to be used in meat and/or poultry products that come under USDA's jurisdiction. Therefore, 21 CFR §170.270 does not apply.

PART 2. IDENTITY, METHOD OF MANUFACTURE, SPECIFICATIONS, AND PHYSICAL OR TECHNICAL EFFECTS

2.A. Scientific Information About the Identity of the Notified Substance

2.A.1. Identity of the Notified Substance

2.A.1.1. Names of the Notified Substance

Common name: Resistant dextrin.

Synonyms or Other Common Names: resistant dextrin-tapioca, resistant dextrin (tapioca), resistant maltodextrin, indigestible dextrin, dextrin (fiber), dietary fiber, tapioca fiber, and soluble tapioca fiber.

Trade name: FiberSMART®, FiberSMART® (tapioca), or FiberSMART®-tapioca.

2.A.1.2. Chemical Names

Chemical Abstract Service Name: Dextrin.

2.A.1.3. Chemical Abstract Service (CAS) Registry Number

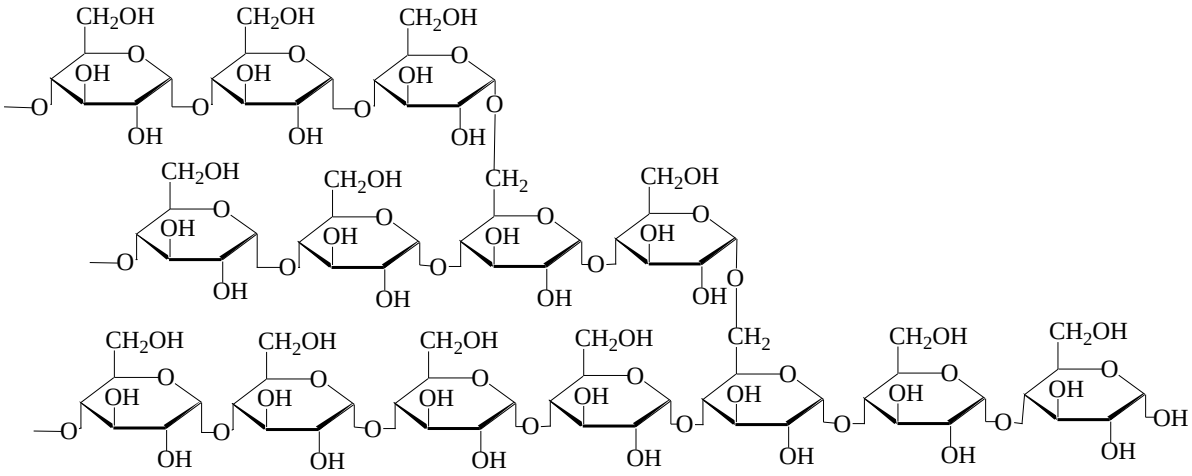
9004-53-9.

2.A.1.4. Empirical Formula

The weight average molecular weight (Mw): 1,732 Daltons.

2.A.1.6. Structural Formula

(a) Starch



(b) Resistant Dextrin

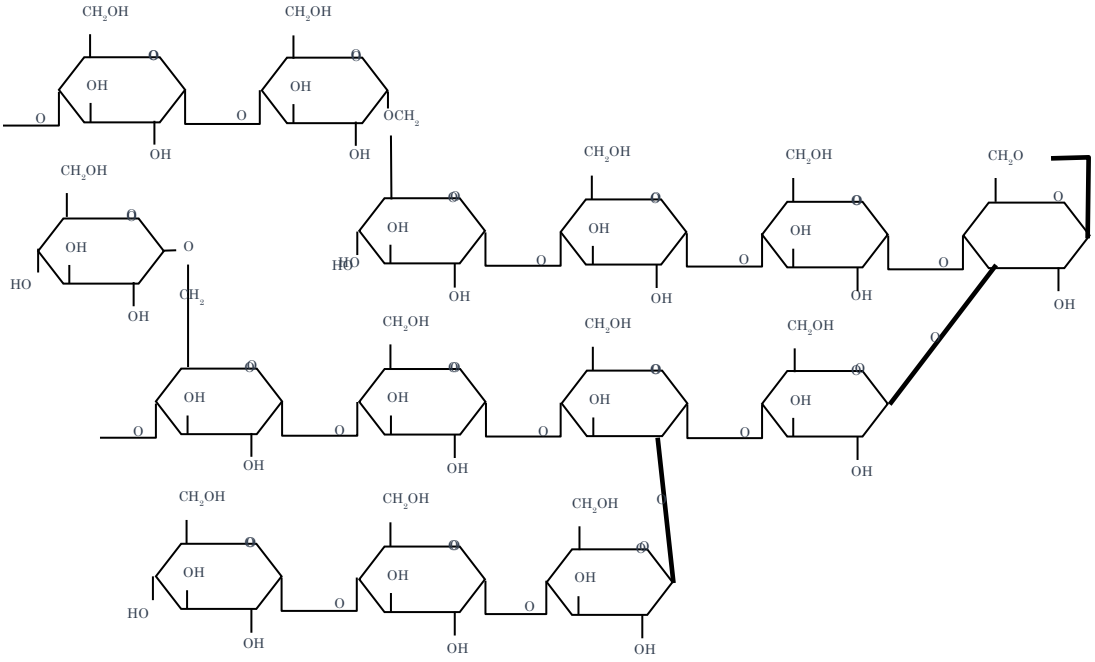


Figure 1. Molecular Structure of Starch (a) and Resistant Dextrin (b)
Resistant dextrin structure, adopted from Hashizume and Okuma (2009)

2.A.1.7. Background

Resistant dextrin, the subject of this GRAS notification, is a specialty dextrin that is produced using a starch hydrolysis and transglucosidation/repolymerization, followed by a series of purification, and spray drying. This process produces an indigestible, mostly soluble dextrin with an elevated fiber content. Thus, it belongs to the non-digestible carbohydrates or dietary fiber category. It is odorless, white or almost white, and non-hygroscopic. AGG's resistant dextrin can be derived from either corn or tapioca starch. The subject of this GRAS determination is resistant dextrin (or FiberSMART®) derived from tapioca starch.

<u>Similarity between Tapioca-Based Resistant Dextrin with Corn- and Wheat-Derived Resistant Dextrins</u>

In June 2018, the FDA acknowledged the resistant dextrin/resistant maltodextrin category (including soluble corn fiber, resistant dextrin, resistant wheat dextrin, soluble wheat fiber, and wheat dextrin; https://www.fda.gov/media/113659/download, pages 49-52) are non-digestible carbohydrates that meet the definition of dietary fiber (FDA, 2018), whose dietary fiber content can be labeled as dietary fiber on food packages.

In the 2016 final rules on Food Labeling: Revision of the Nutrition and Supplement Facts Labels (FDA, 2016a), FDA stated the following: "We consider AOAC 2009.01 and AOAC

2011.25 to be reliable and appropriate methods to measure the amount of dietary fiber in a serving of a product" (page 33,960 of Federal Register. 2016; 81 (103), May 27, 2016). Dietary fiber values measured by these methods can be used to determine compliance consistent with §101.9(g). Thus, similar dietary fiber contents in resistant dextrin ingredients measured by AOAC 2009.01 or 2011.25 would justify the equivalence of corn-, tapioca-, or wheat-derived dextrin although there are variations in degree of polymerization (DP) units. In other words, equivalence of corn-, tapioca-, or wheat-derived dextrin is mostly justified from the aspect of its dietary fiber content. Regardless of its sources, powder forms of resistant dextrins have a dietary fiber content of 65-90%, as measured by AOAC 2009.01 or 2011.25.

Resistant dextrins (pyrodextrins) are made from corn-, wheat-, or tapioca-starch by pyrodextrinization with or without enzyme treatments for purification purposes after pyrodextrinization. In the presence of various resistant dextrin preparations, different companies use different terms to describe these ingredients manufactured under the same principle, pyrodextrinization of hydrolyzed starch under acidic heat treatments of overdried starches. The term 'resistant dextrin' is used by AGG and Roquette under the brand names of 'FiberSMART®' and 'NUTRIOSE' (NUTRIOSE FM, derived from corn; NUTRIOSE FB, wheat based), respectively. The term 'resistant maltodextrin' is used by Matsutani Chemical Industry under the brand names of 'Fibersol-2' and 'Pinefibre-C.' The term 'soluble corn fiber' is used by Tate & Lyle under the brand name of 'PROMITOR'. Manufacturing processes of polydextrose and isomaltodextrin are based on different manufacturing principles (by enzymatic or dehydration synthesis), but the end finished products have similar properties.

Table 2 compares the total fiber content, DP, and molecular weights of these dietary fiber ingredients. Dietary fiber content can be controlled by the degree of purification. As shown in Table 2, the dietary fiber content, a key compliance marker for nutrition labeling purposes, are comparable between AGG's resistant dextrin (FiberSMART®) and other sources of resistant dextrins (Nutriose; derived from corn- or wheat-starch) and polydextrose. In addition, DP, average molecular weight, and polydispersity are comparable among these ingredients (Table 2). Details of are shown in Annex A.

Pyrodextrinization results in a drastically reduced molecular weight and the introduction of new glucoside linkages. Unlike starches which contain only "digestible" α- linkages (95% α-1,4 and 5% α-1,6), resistant dextrins contain "nondigestible" α-1,2, β-1,6, β-1,4, and β-1,2 glycosidic linkages. In resistant dextrin-tapioca, α-1,4-, α-1,6-, and α-1-2-linkages contribute 37-48%, 16-21%, and 2.7-4.1%, respectively, and β-linkages contribute 26-31% of total glycosidic linkages, respectively (Trithavisup et al., 2021). This glycosidic linkage composition of AGG's resistant dextrin-tapioca is comparable to the literature value (Trithavisup et al., 2021). AGG's resistant dextrin consists of 67.7% and 32.3% of α- and β-linkages, respectively. Details of linkage analysis are presented in Annex B.

Table 2. Compositional Comparison Between AGG's Resistant Dextrin with Other Products

Parameters	NUTRIOSE® 6	NUTRIOSE® 10	FiberSMART®	Polydextrose[1]
DP	12-25	4-10	Average, 10.6	12
M_n	2,000-4,000	800-1,500	767	800
M_w	4,000-6,000	3,500-4,500	1,732	2,000
Polydispersity (M_n/M_w)	1.5-2.5	3-4.5	2.05	2.5
Total Dietary Fibers, %	Average, 85	Average, 70	Average, 86	90

Modified from Table 1, GRN 436 (stamped page 10).

[1]Craig SAS, Holden JF, Troup JP, Auerbach MH, Frier HI. (1998) Polydextrose as soluble fiber: Physiological and analytical aspects. Cultor Food Science, Ardsley, NY. American Association of Cereal Chemists, Inc.

DP=degree of polymerization; M_n = the number average molecular weight; Mw= the weight average molecular weight;

Standards of Identity

In this notice, AGG states its intention to use resistant dextrin in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

2.A.2. Potential Toxicants in the Source of the Notified Substance

No toxicant production is expected in the manufacture of resistant dextrin (tapioca). The raw material, tapioca starch, is free of mycotoxins and pesticides (Annex C). In addition, AGG's resistant dextrin (FiberSMART®) derived from tapioca does not have cyanogenic glycosides (Annex D).

2.A.3. Particle Size

To check the particle size of AGG's resistant dextrin, 3 non-consecutive batches were passed through a series of U.S. mesh screens. Approximately 99% and 99.9% of the AGG's resistant dextrin powders passed through U.S. mesh screen size 60 and 40, respectively. The data indicate that the particle size is less than 470 micron.

2.B. Method of Manufacture

Although various starch sources have been and can be used in the manufacture of resistant dextrins, the subject of this GRAS determination is resistant dextrin derived from tapioca starch.

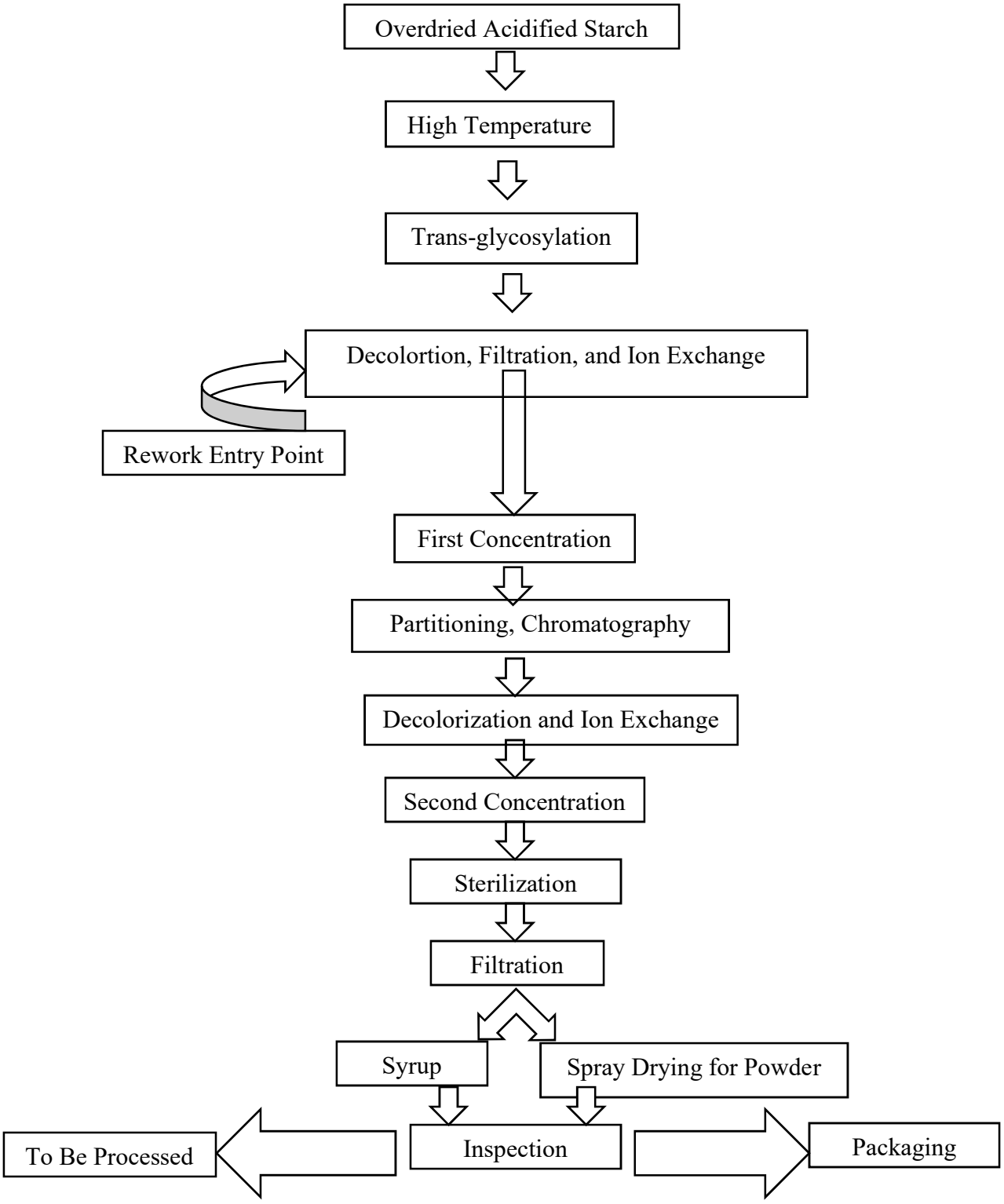
Resistant dextrin is made by a combination of hydrolysis and transglucosidation/repolymerization processes. Roasting dry starch at acidic conditions results in hydrolysis of the α-1,4 and α-1,6 glycosidic bonds, resulting in shorter starch molecule chain. In the absence of sufficient water, the freed glucose linkages combine within themselves and trans-glucosidation/repolymerization occurs creating random glycosidic linkages such as β-1,4, β-1,6, and β-1,2. Due to the fact that the resulting pyrodextrin contains nondigestible linkages that are not hydrolyzed by human digestive enzymes, the reaction product is called resistant dextrin (or resistant maltodextrin).

The resulting resistant dextrin is subjected to sequential purification: activated carbon treatment for decolorization, filtration, ion exchange chromatography, concentration, partitioning chromatography, second decolorization and ion exchange chromatography, second concentration, sterilization, filtration, spray drying, and packaging to make a powder form of AGG's resistant dextrin. The resistant dextrin syrup can be made by skipping the spray drying process. The number of mono- and disaccharides (DP1 and DP2) can be controlled via the separation process. The flow diagram of the manufacturing process is presented in Figure 2.

<u>Quality Assurance Procedure:</u>

AGG rigorously tests its final production batches to verify adherence to quality control specifications. AGG's resistant dextrin is manufactured consistent with the principles of current Good Manufacturing Practice (cGMP) for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade. AGG routinely evaluates the quality of the resistant dextrin during the production process to ensure that the finished ingredients are free of contaminants.

Figure 2. Flow Diagram of Manufacturing Process for AGG's Resistant Dextrin



The manufacturing process of AGG's resistant dextrin (tapioca) is similar to that described in GRN 436 with the exception of skipping enzymatic treatment (alpha-amylase or glucoamylase to remove digestible carbohydrates) after pyrodextrinization. There is a report demonstrating that the chemical characteristics and molecular weight of resistant dextrin did not change significantly by purification processes (Zhen et al., 2021). Table 3 summarizes the manufacturing processes employed for various resistant dextrin preparations.

Table 3. Summary of Manufacturing Processes Employed for Various Resistant Dextrins

	GRN 436	Current notice
Starting material	Corn or wheat starch	Tapioca starch
Acid hydrolysis	Yes	Yes
Enzyme treatments after converting into pyrodextrin, but before purification	Yes	No
Partition chromatography	Yes/No	Yes
Dietary fiber content with both partition chromatography and ion chromatography	82-88 g/100 g	85-87 g/100 g
Dietary fiber content with ion chromatography only (no partition chromatography)	65-75 g/100 g	Not applicable

AGG analyzes all incoming raw materials periodically for compliance with their published specifications.

2.C. Composition and Specifications of AGG's Resistant Dextrin and Their Raw Materials

Table 4 shows the specifications of AGG's Resistant Dextrin. The dietary fiber content of AGG's resistant dextrin ranges from 85 to 87% for the powder form (Table 5). These values are comparable to other corn- or wheat-derived resistant dextrin reported in GRN 436: ranged from 82 to 88%. Analyses of three non-consecutive lots of AGG's resistant dextrin confirm that both powder and syrup forms of AGG's resistant dextrin are consistent and comply with the product specifications. Powder and syrup forms of AGG's resistant dextrin have over 80% and 60% of total dietary fiber, respectively. The certificates of analysis (COAs) are shown in Annex E.

Table 4. Specifications for AGG's Resistant Dextrin

	Tapioca		Method of Analysis
	Powder	Syrup	
Appearance	White powder	Yellowish syrup	Visual
Total Dietary Fiber, g/100 g	≥80	≥60	AOAC 2011.25 or 2009.01
Moisture, g/100 g	≤6.0	≤28.0	AOAC 945.43, AOAC 2015.06
As, mg/kg	<0.2	<0.2	ICP MS: AOAC 993.14, AOAC 2015.06
Cd, mg/kg	<0.2	<0.2	
Pb, mg/kg	<0.2	<0.2	
Aerobic Plate Count, CFU/g	<1,000	<1,000	FDA BAM Ch. 3
Molds, CFU/g	≤10	≤10	FDA BAM Ch. 18, Compendium
Yeasts, CFU/g	≤10	≤10	FDA BAM Ch. 18, Compendium
Salmonella, /25 g	Absent	Absent	AOAC 2013.01

AOAC=Association of Official Analytical Communities; BAM= Bacteriological Analytical Manual; Ch=chapter; ICP MS= Inductively coupled plasma mass spectrometry.

Table 5. Analytical Values for AGG's Resistant Dextrin Powder

Parameters	20200622037	2020090717	20191007034
Total Dietary Fiber, g/100 g	87.0	85.2	85.6
Total Sugars, g/100 g	0.58	0.73	0.82
Moisture, g/100 g	5.1	4.0	5.9
Ash, g/100 g	<0.012	0.028	0.036
Total Fat, g/100 g	<LOQ	<LOQ	<LOQ
Protein, g/100 g	<0.781	<0.781	<0.781
Carbohydrates, g/100 g	94.9	96.0	94.1
Arsenic, µg/kg	<10	<10	<10
Cadmium, µg/kg	<10	<10	<10
Lead, µg/kg	<10	<10	<10
Mercury, µg/kg	<4	<4	<4
Aerobic Plate Count, CFU/g	<10	<10	<10
Molds, CFU/g	<10	<10	<10
Yeasts, CFU/g	<10	<10	<10
Salmonella, /25 g	Negative	Negative	Negative

Table 6. Analytical Values for AGG's Resistant Dextrin Syrup

Average	20191106013	20200303033	20210311023
Total Dietary Fiber, g/100 g	65.6	65.4	65.6
Total Sugar, g/100 g	0.64	0.97	0.88
Moisture, g/100 g	27.8	27.8	28.3
Ash, g/100 g	<0.012	<0.012	<0.012
Total Fat, g/100 g	<LOQ	<LOQ	<LOQ
Protein, g/100 g	<0.781	<0.781	<0.781
Carbohydrates, g/100 g	72.2	72.1	71.7
Arsenic, ng/kg	<10	<10	<10
Cadmium, ng/kg	<10	<10	<10
Lead, ng/kg	<10	<10	<10
Mercury, ng/kg	<4	<4	<4
Aerobic Plate Count, CFU/g	<10	<10	<10
Molds, CFU/g	<10	<10	<10
Yeasts, CFU/g	<10	<10	<10
Salmonella, /25 g	Negative	Negative	Negative

2.D. Intended Technical Effects

AGG's resistant dextrin is intended to use as a food ingredient in selected conventional foods and beverages.

PART 3. DIETARY EXPOSURE

3.A. Estimated Daily Intakes (EDIs) of Resistant Dextrin Under the Intended Use

Resistant dextrin is proposed for use as a food ingredient. AGG's resistant dextrin is intended to be used in the following food categories at approximately 1.2 to 10 g/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 including processed dried fruits; (14) shelf-stable desserts; (15) snacks and crackers; (16) dry beverage powder; and (17) nutrition bars. The new category, nutrition bars, has been added to the intended use and use levels listed in GRN 436.

The EDI of resistant dextrin were calculated using food consumption data for the 17 food categories from the most recent National Health and Nutrition Examination Surveys (NHANES) conducted in 2017-2018. Nearly all people in the total United States (U.S.) population reported eating at least one food proposed for resistant dextrin (% all-users, >98%). As a result, the mean and 90th percentile per user intakes are close to their per capita values; the mean per user is 14.4 g/day and 90th percentile per user is 26.5g/day. The per user 90th percentile for the various age and gender subgroups ranged from 17.2 g/day (children aged 2 to 5 years) to 31.5 g/day (males 19+ years) (Table 7). These EDI values are lower than those described in GRN 436 in which the mean and 90th percentile EDIs were 17.4 and 32.9 g/day in all population, respectively.

The differences in the EDI values between our analysis and GRN 436 are probably due to the following reasons:

1) Our analysis for 2015-2018 used the RACC values available from the latest values published by the FDA in 2020 (https://www.fda.gov/food/new-nutrition-facts-label/serving-size-updates-new-nutrition-facts-label). The values for RACC in the revised regulations are often larger than the ones used for GRN 436. For example, for food codes 94100100 'water, bottled, unsweetened' and for 92101000 'coffee, brewed', the RACCs used in GRN 436 and this analysis were 240 mL and 360 mL, respectively. If GRN 436 used 3 g per 8 oz drink and we use 3 g per 12 oz drink, then we would get 33% less in mean EDIs from non-dairy beverages. There were a large number of consumptions for each of these food codes. When the intended use is in grams per RACC, a larger RACC leads to smaller use levels per gram of food, which is reflected in the smaller EDIs in this analysis.

2) Many food codes used in GRN 436 (NHANES 2003-2006) have been dropped and are no longer available in the 2015-2018 NHANES dataset.

3) In GRN 436, intended use levels of some dry powder products exceeded the serving size. For example, it was indicated that 9 g resistant dextrin was in dry instant coffee powder products, whose serving size is 2.4 g (corresponding food codes; NHANES food codes-92191000, 92191100, 92191200, and 92191300). AGG intends to use 1.2 g resistant dextrin in these dry instant coffee powders.

4) Additionally, methods and participants of different dietary survey sets may have contributed some variability in the analytical results of the survey.

These EDIs are overly inflated due to the following reasons: it is not expected that the actual consumption of foods containing resistant dextrin will result or even approach a daily consumption of the daily reference value (DRV) for fiber of 28 g/day. Despite the introduction of newly developed dietary fiber ingredients, an average American has consumed approximately one half of the recommended intakes. Americans' mean per capita dietary fiber intake is only 15.5-16.2 g per day or approximately 58% of the recommended intakes, indicating that actual intake levels are far below the theoretical, optimistic EDI values. In addition, AGG's resistant dextrin is expected to replace currently available total fiber sources. Thus, it is not expected that the cumulative EDIs are expected to be changed. Equally important, the Institute of Medicine (IOM, 2005) has not established a tolerable upper limit for dietary fiber.

Table 7. EDIs of Resistant Dextrin

Population Group	All-Person Intake		All-Users Intake			
	Mean	90th Pctl	% Users	n	Mean	90th Pctl
g/person/day						
2-5 y	10.2 ± 0.26	17.2 ± 0.40	99.9	996	10.2 ± 0.26	17.2 ± 0.40
6-12 y	11.9 ± 0.40	21.0 ± 0.61	99.7	1,738	11.9 ± 0.36	21.0 ± 0.61
13-18 y	12.9 ± 0.36	23.7 ± 0.72	98.7	1,416	13.1 ± 0.37	23.9 ± 0.86
13-18 y M	14.0 ± 0.56	25.8 ± 1.44	99.4	713	14.1 ± 0.54	25.9 ± 1.44
13-18 y F	11.8 ± 0.52	21.5 ± 0.84	98.1	703	12.0 ± 0.52	21.8 ± 0.82
19-99 y	14.9 ± 0.20	28.2 ± 0.70	99.0	8,277	15.1 ± 0.20	28.2 ± 0.73
19-99 y M	16.47 ± 0.22	31.5 ± 0.58	98.7	4,021	16.7 ± 0.20	31.5 ± 0.60
19-99 y F	13.4 ± 0.27	24.4 ± 0.62	99.2	4,256	13.6 ± 0.28	24.5 ± 0.62
2-99 y	14.2 ± 0.18	26.4 ± 0.56	99.1	12,427	14.4 ± 0.17	26.5 ± 0.56
mg/kg bw/day						
2-5 y	600 ± 14	1,047 ± 29	98.5	981	601 ± 14	1,048 ± 28
6-12 y	359 ± 12	642 ± 23	99.4	1,729	360 ± 12	642 ± 23
13-18 y	199 ± 6.1	375 ± 17	98.0	1,407	202 ± 6.2	376 ± 17
13-18 y M	209 ± 8.5	416 ± 28	99.0	711	210 ± 8.2	416 ± 28
13-18 y F	190 ± 9.0	348 ± 22	97.1	696	194 ± 8.8	349 ± 21
19-99 y	187 ± 2.9	352 ± 6.7	98.3	8,198	189 ± 2.8	353 ± 7.0

19-99 y M	191 ± 3.4	357 ± 8.0	97.9	3,979	193 ± 3.2	361 ± 7.5
19-99 y F	183 ± 3.9	345 ± 11	98.7	4,219	185 ± 4.0	347 ± 11
2-99 y	226 ± 3.6	446 ± 8.4	98.4	12,315	228 ± 3.5	447 ± 8.0

Based on the 2017-2018 NHANES dataset; F = females; M = males; pctl = percentile; y = years.

Americans' Dietary Fiber Intake Status

Based on the analysis of the NHANES datasets, King et al. (2012) reported that the mean daily dietary fiber intakes for 1999-2000 and for 2007-2008 were 15.7 and 15.9 g/day, respectively (Table 8). The analysis of the 2017-2018 NHANES dataset showed that an average American's dietary fiber intake (age 2 years and above) was 16.2 g/day, ranging from 15.7 for non-Hispanic whites to 19.5 g for Asians (https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1718/Table_ 1_ NIN_GEN_17.pdf).

Table 8. Americans' Dietary Fiber Intake Status in the Past 2 Decades

	Per capita mean intake of dietary fiber, g/day
1999-2000[a]	15.7
2007-2008 [a]	15.9
2015-2016[b]	16.5
2017-2018[b]	16.2

[a]From King et al. (2012).
[b]From What We Eat in America, 2015-2016 and 2017-2018 datasets, available at https://www.ars.usda.gov/arsuserfiles/80400530/pdf/1516/table_1_nin_gen_15.pdf; 2017-2018, and https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1718/Table_1_NIN_GEN_17.pdf, respectively.

Although dietary fiber intake levels appear to be slightly increased over time, contribution of analytical method changes cannot be ignored. The dietary fiber database available in older NHANES datasets was based on conventional dietary fiber methods, such as AOAC 985.29 and 991.43, which do not capture non-digestible oligosaccharides to be in line with the previous traditional definition of dietary fiber measured as the sum of non-starch polysaccharides and lignins. The newer dietary fiber methods, such as 2011.25 or 2009.01, include non-digestible oligosaccharides in addition to dietary fiber components meeting the traditional definition of dietary fiber, such as non-starch polysaccharides and lignins. Recently, the FDA has adopted the new definition of dietary fiber, including non-digestible oligosaccharides (DP≥3) proposed by the IOM (2001) for labeling purposes.

Considering the changes in dietary fiber analytical methods, dietary survey data collection methods, and other variables, it appears that the total dietary fiber intake status has not been significantly changed in the past 2-3 decades despite the fact various new dietary fiber ingredients have been introduced in the marketplace. Resistant dextrin is a typical example which has been newly introduced in the American marketplace since early 2000s. The data

indicate that the introduction of resistant dextrins, new ingredients providing ≥60 to ≥80% dietary fiber, has had a minor impact on the Americans' total dietary fiber intake status. It is probably due to the fact that most of the resistant dextrins have been used to replace existing dietary fiber ingredients in food formulations.

3.B. Food Sources of Resistant Dextrin

Pyrodextrinization does not usually occur in conventional food processing condition; thus, it is reasonable to assume that negligible amounts of resistant dextrins are present in conventional foods.

3.C. EDIs of Naturally Occurring Resistant Dextrin from Diet

No applicable.

Summary of Consumption Data

AGG's resistant dextrin is intended to be used in the following food categories at approximately 1.2 to 10 g/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 including processed dried fruits; (14) shelf-stable desserts; (15) snacks and crackers; (16) dry beverage powder; and (17) selected nutrition bars. These 17 food categories were selected as the most common potential use example applications for this ingredient in order to generate the most accurate consumption data.

The mean intake from all the selected food categories was 14.4 g/day and the 90th percentile intake was 26.5 g/day in all-users. FDA has established a DRV for fiber as 28 g/day.

PART 4. SELF-LIMITING LEVELS OF USE

No known self-limiting levels of use are associated with resistant dextrin.

PART 5. HISTORY OF CONSUMPTION

EXPERIENCE BASED ON COMMON USE IN FOODS BEFORE 1958

The statutory basis for the conclusion of the GRAS status of resistant dextrin in this document is not based on common use in food before 1958.

PART 6. NARRATIVE

6.A. Current Regulatory Status

The resistant dextrin/maltodextrin are being commercialized under 21 CFR §184.1277 (dextrin) and 21 CFR §184.1444 (maltodextrin).

The FDA has issued a 'no question' letter on a GRAS notification related to food use of resistant dextrins (GRN 436; FDA, 2013) as well as other "resistant" polyglucose ingredients such as polydextrose (21 CFR §172.841) and isomaltodextrin (GRN 610; FDA, 2016b). All these products are manufactured from starch or other glucose-based sources using various methods but result in similar substances.

On May 27, 2016, FDA issued two final rules (FDA, 2016a) to revise the nutrition labeling requirements for conventional foods. The final rule incorporates two major changes to the dietary fiber declaration—a definition of "dietary fiber" and an increase in the DRV from 25 grams to 28 grams.

The final definition of total fiber is: "non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health." The final definition distinguishes between "isolated *or* synthetic" non-digestible carbohydrates from intrinsic dietary fibers naturally present in foods or food ingredients. FDA uses "isolated" to describe "non-digestible carbohydrates that are isolated from plant sources such that they are no longer intrinsic or intact" and "synthetic" to describe "synthetic non-digestible carbohydrates that are not isolated from plant sources but rather chemically synthesized." Resistant dextrins may be considered as synthetic non-digestible carbohydrates that meet the definition of total dietary fiber.

In April 2018, based on the review of physicochemical and physiological properties of resistant dextrins, FDA approved resistant dextrin/resistant maltodextrin as non-digestible carbohydrates that meet the dietary fiber definition (FDA, 2018, pages 49 to 52).

The IOM (2005) recommends that Americans increase their dietary fiber intakes and has not established a Tolerable Upper Intake Level (UL) for dietary fiber. The ULs reflect the maximum daily intake levels at which no risk of adverse health effects is expected for almost all individuals in the general population including sensitive individuals when the substance is consumed over long periods of time. In other words, the UL is the highest usual intake level of a substance that poses no risk of adverse effects.

6.B. Review of Safety Data

Resistant dextrin contains random glycosidic linkages, such as β-1,4, β-1,6, β-1,2, and α-1,2 that are resistant to hydrolysis by human alimentary enzymes. Because of this resistance and solubility in water, resistant dextrin is classified as a dietary fiber.

As noted above in Part 6.A, the FDA has issued a 'no question' letter on a GRN related to food uses of resistant dextrins (GRN 436, enzyme-modified dextrins or resistant dextrins, NUTRIOSE FM, derived from corn; NUTRIOSE FB, wheat-based; Roquette). As the resistant dextrin in this GRAS determination is similar in specifications compared to other sources of resistant dextrins (NUTRIOSE 6 providing an average of 85% dietary fiber; NUTRIOSE 10 providing an average of 70% of dietary fiber) described in the previous FDA GRAS notice, GRN 436, it is recognized that the information and data in GRN 436 are pertinent to the safety of the resistant dextrin in this GRAS determination. Therefore, this notice incorporates, by reference, the safety and metabolism studies discussed in GRN 436. This notice incorporates by reference the safety and metabolism studies discussed in GRN 436 (pages 18-26) and will not discuss previously reviewed references in detail. In addition, mutagenicity, acute toxicity, and a 90-day oral toxicity studies of AGG's resistant dextrin are reviewed in this notice. The subject of the present GRAS assessment is resistant dextrin derived from tapioca or FiberSMART® -tapioca. Our review covers the literature published up to October 31, 2021.

6.B.1. Metabolism

It is reasonable to conclude that resistant dextrin follows the general metabolic fate of dietary fiber. Thus, resistant dextrin is expected to escape the hydrolysis by human alimentary enzymes and to reach the colon where it is fermented by microflora to produce short-chain fatty acids (SCFAs). Fermentation of soluble dietary fiber provides fecal bulking effects and some calorie values (Slavin, 2008). The FDA guidance of soluble fiber is 2 kcal/g, as opposed to 4 kcal/g for digestible carbohydrates, for labelling purposes (FDA, 2016a).

6.B.2. Mutagenicity and Genotoxicity Studies

A Mutagenicity Study of AGG's Resistant Dextrin (derived from corn and tapioca starches)

In the study by Case et al. (2021), AGG's FiberSMART® preparations (derived from corn and tapioca starches) were tested for mutagenicity using *Salmonella typhimurium* TA98, TA100, TA1535, or TA 1537 with or without S9 activation (Table 9). The test concentrations were 0, 1,250, 2,500, and 5,000 μg/plate. 4-Nitro-o-phenylenediamine (NPD), daunomycin (DAM), sodium azide (NaN_3), and methyl methanesulfonate (MMS) were used as the positive controls in the absence of the S9 mix, and 2-aminofluorene (2-AF), 1,8-dihydroxyanthraquinone (1,8-DT; also known as dantron), and 2-aminoanthracene (2-AA) were used as the positive controls in the

presence of the S9 mix. The test substance was considered mutagenic if the number of revertant colonies in the test dose levels was more than twofold that of the control, or if the number of revertant colonies increased in a dose-dependent manner compared to the control in at least one strain with or without metabolic activation. The validity of the study was confirmed by more than two-fold increases in the number of revertant colonies in the positive control plates compared to the control. Resistant dextrins derived from corn or tapioca did not increase the number of revertant colonies in any tester strains in the absence or presence of metabolic activation by the S9 mix. The data indicated that both types of resistant dextrins (corn and tapioca based) were not mutagenic under the conditions used in the test.

A Study Reviewed in GRN 436

There was no mutagenicity of resistant dextrin (wheat; Nutriose® FB), at concentrations up to 5,000 μg/plate, in TA98, TA100, TA102, TA1535, and TA1537 with or without S9 activation (Wils et al., 2008). In addition, a mutation assay at the TK locus in L5178Y mouse lymphoma cells did not show a mutagenic potential of resistant dextrin-wheat.

Overall, resistant dextrins, regardless of their sources, did not show mutagenic potential.

Table 9. Bacterial Mutation Assay Results for AGG's Resistant Dextrin

	Dose (μg/plate)		Mean Revertant Colony Counts Per Plate				
			TA97	TA98	TA100	TA102	TA1535
-S9	Vehicle control		110.7±10.7	34.3±5.9	203.7±15.6	261.3±21.4	63.0±24.6
	RD-corn	5,000	123.7±9.6	26.3±8.5	177.3±22.0	248.7±19.7	70.0±31.2
		2,500	103.7±18.1	30.0±5.0	186.7±3.8	275.0±28.2	78.0±24.3
		1,250	97.3±11.2	23.3±5.5	201.0±34.4	288.0±27.2	88.7±39.9
	RD-tapioca	5,000	108.7±20.6	27.7±2.1	206.7±25.0	270.3±24.5	94.3±11.2
		2,500	106.0±8.9	31.3±4.0	204.3±19.8	289.7±45.5	111.0±25.6
		1,250	112.7±17.1	30.0±4.0	182.7±39.1	278.0±24.00	71.3±15.6
	NPD	20	1,084.0±113.5**	—	—	—	—
	DAM	10	—	861.7±199.9**	—	—	—
	NaN_3	1.5	—	—	1,168.3±198.3**	—	866.3±45.7**
	MMS	2	—	—	—	926.3±169.5**	—
+S9	Vehicle control		152.7±7.1	42.0±5.2	243.0±20.4	309.0±23.6	96.0±25.9
	RD-corn	5,000	128.3±6.7	45.7±5.9	218.0±6.9	289.7±10.5	115.0±12.0
		2,500	147.0±13.1	40.0±6.1	257.3±46.1	311.0±22.6	113.3±23.4
		1,250	137.0±4.0	42.0±3.5	227.7±9.3	318.0±2.0	124.0±10.1
	RD-tapioca	5,000	127.7±14.8	38.3±2.3	219.7±31.9	261.7±28.7	148.7±26.3
		2,500	133.0±8.2	24.3±2.1	209.7±10.6	298.3±25.9	143.3±22.0
		1,250	161.3±12.2	43.7±10.6	192.3±8.3	300.7±9.3	95.0±1.7
	2-AF	20	836.3±24.0**	958.0±48.5**	1,032.3±37.6**	—	—
	1,8-DT	50	—	—	—	505.0±39.3**	—
	2-AA	5	—	—	—	—	438.7±22.1**

Adopted from Case et al. (2021).

Abbreviations: 1,8-DT = 1,8-dihydroxyanthraquinone (also known as dantron); 2-AA = 2-aminoanthracene; 2-AF = 2-aminofluorene; DAM = daunomycin; MMS = methyl methanesulfonate; NaN_3 = sodium azide; NPD = 4-Nitro-o-phenylenediamine.

**P<0.01, compared with vehicle control.

6.B.3. Animal Toxicity Studies

Table 10 summarized the animal toxicity studies conducted on AGG's FiberSMART® and other sources of resistant dextrins.

Table 10. Summary of Animal Toxicity Studies

Test Material	Animal	Dose	Duration	LD_{50} or NOAEL	Reference
Acute Toxicity Studies					
RD derived from tapioca (AGG's FiberSMART®-tapioca or corn)	30 SD rats	0 or 20 g/kg bw, FiberSMART®-corn (source, corn)	Single dose, 14 d observation	LD_{50}> 20.0 g/kg bw	Case et al, 2021
		20 g/kg bw, FiberSMART®-tapioca (source, tapioca)		LD_{50}> 20.0 g/kg bw	
RD derived from wheat (brand name, Nutriose® FB	5 fasted female SD rats	2 g/kg bw resistant dextrin (source, wheat)	Single dose	LD_{50}> 2 g/kg	Wils et al., 2008
RD derived from corn or tapioca	Rats	NA	NA	LD_{50}> 40.0 g/kg bw	Hashizume and Okuma, 2009
Subchronic Toxicity Studies					
RD derived from tapioca (brand name, AGG's FiberSMART®-tapioca)	88 SD rats	0, 1,250, 2,500, or 5,000 mg/kg bw/d	90 d	NOAEL, 5,000 mg/kg bw/d for both male and female rats	Case et al., 2021
RD derived from wheat (brand name, Nutriose® FB)	160 OFA-SD rats	0, 1,120, 2,290, or 4,360 mg/kg bw/d (males)	90 d	NOAEL, 4,360 mg/kg bw/d (males)	Wils et al., 2008
		0, 1,610, 3,080, or 6,500 mg/kg bw/d (females)		NOAEL, 6,500 mg/kg bw/d (females)	

NA=not available; RD=resistant dextrin; SD= Sprague–Dawley.

6.B.3.1. Animal Toxicity Studies of AGG's Resistant Dextrins

Acute Toxicity Study of AGG's Resistant Dextrin (Table 10)

The acute oral toxicity of AGG' resistant dextrins, FiberSMART® (tapioca starch and corn starch-based), was studied in six-week-old Sprague-Dawley (SD) rats (Case et al., 2021). The animals were orally administered by gavage at a single dose of 0 or 20 g/kg body weight (bw) of corn- or tapioca-based resistant dextrin and were observed for 14 days to monitor changes in body weight, clinical signs, and food and water consumption. No animals died during the 14-day observation period. No abnormal clinical signs or no significant differences in mean body weight, food and water intake, and organ weights were found in both control and test groups. No treatment-related abnormalities were observed in macroscopic or microscopic examinations. The mean lethal dose (LD_{50}) of both types of FiberSMART® (RD-corn and RD-tapioca) was well above 20 g/kg bw, the highest dose tested. The data indicate that both types of resistant dextrins are 'relatively harmless' (Altug, 2003).

Subchronic Toxicity Study of AGG's Resistant Dextrin

In the subchronic toxicity study, SD rats were administered 0, 1,250, 2,500, or 5,000 mg/kg bw/day resistant dextrin-tapioca by gavage for 90 days. The study protocol was adopted from the Organization for Economic Co-operation and Development (OECD) guidelines test number 408.

At any dose level, no clinical signs of toxicity or mortality were observed. No differences in body weight and feed consumption were observed between the groups. Urinalysis did not show any treatment-related adverse effects. Although some parameters showed significant differences, they were not considered of toxicological significance because they did not occur in both sexes, were not dose-dependent, and/or were within the laboratory's historical normal range of controls (Tables 11 to 14). Thus, the authors stated that no clinically significant treatment-related abnormalities were found in hematology, clinical chemistry, and absolute and relative organ weights in any of the resistant dextrin-tapioca (FiberSMART®) treated groups. The authors concluded that the No Observed Adverse Effect Level (NOAEL) was 5,000 mg/kg bw/day, the highest dose tested, for male and female rats. Detailed data are presented in Case et al. (2021).

Table 11. Hematologic Findings in Male and Female Rats Treated with AGG's Resistant Dextrin

Parameter	Male (mg/kg bw/day)				Female (mg/kg bw/day)			
	Control	1,250	2,500	5,000	Control	1,250	2,500	5,000
WBC ($x10^9$/L)	4.77±0.85	4.32±0.86	4.10±0.72	4.18±0.85	3.06±0.90	3.13±0.87	3.03±0.57	2.99±0.47
Hb (g/L)	15.7±0.9	16.2±0.8	16.1±0.5	16.5±1.0	15.0±1.1	15.0±0.5	14.9±1.0	15.1±0.7
HCT (%)	48.5±2.8	50.1±2.7	49.8±1.6	50.7±3.0	45.9±3.8	43.5±9.5	45.5±3.3	46.6±2.2
RBC ($x10^{12}$/L)	9.41±0.63	9.75±0.46	9.68±0.31	9.81±0.52	8.46±0.61	8.00±1.79	8.53±0.67	8.59±0.44
MCV (fL)	51.6±1.66	51.41±0.81	51.79±0.81	51.65±1.19	54.18±1.02	54.48±1.42	53.37±1.65	54.21±1.54
MCH (Pg)	16.7±0.53	16.60±0.41	16.58±0.24	16.70±0.50	17.75±0.46	17.65±0.52	17.45±0.63	17.53±0.63
MCHC (g/L)	32.3±0.49	32.29±0.44	32.11±0.25	32.17±0.26	32.75±0.71	32.41±0.74	32.66±0.33	32.35±0.84
PLT ($x10^9$/L)	991.0±103.6	1,019.6 ±90.0	1,083.2 ±135.2	1,091.7 ±109.9*	850.9 ±167.5	858.8 ±104.8	956.6 ±143.6	983.7 ±134.3
NEUT (%)	17.5±7.3	20.1±4.4	19.2±5.3	16.2±4.9	14.9±11.0	18.2±10.2	19.3±7.0	16.8±10.4
LYMPH (%)	74.2±8.3	70.9±5.8	72.0±5.8	75.7±5.6	76.1±13.5	73.2±10.2	71.5±9.2	73.7±12.1
MONO (%)	6.37±2.34	6.57±1.51	5.85±0.99	6.15±1.25	7.17±2.30	7.11±1.85	7.22±3.02	7.57±1.82
RET (%)	2.76±0.37	2.45±0.38	2.66±0.27	2.57±0.24	2.65±0.72	3.00±0.87	2.73±0.45	2.97±0.96

Adopted from Case et al. (2021); The study was sponsored by AGG. Values were mean±SD.

Hb = hemoglobin; HCT = hematocrit; LYMPH = lymphocytes; MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume; MONO = monocytes; NEUT = neutrophils; PLT = platelet count; RBC = red blood cell; RET = reticulocytes; WBC = white blood count.

*P<0.05 vs. control group.

Table 12. Plasma Biochemistry in Male and Female Rats Treated with AGG's Resistant Dextrin

Parameters	Male (mg/kg bw/day)				Female (mg/kg bw/day)			
	Control	1,250	2,500	5,000	Control	1,250	2,500	5,000
TP (g/L)	62.2 ± 6.6	65.9±5.0	59.6±5.9	62.2±7.4	67.5±4.7	62.1±5.6*	68.2±4.3	65.7±7.5
ALB (g/L)	33.4± 3.5	32.8±4.7	36.2±3.9	30.0±4.9	39.5 ±4.9	42.2±3.6	36.1±4.7	38.5±5.4
ALT (U/L)	36.6±5.2	37.1±5.9	35.3±8.5	39.3±8.9	32.8±5.3	33.9±4.7	31.7±5.3	31.1±4.9
AST (U/L)	122.7±15.0	129.6±14.3	115.6 ±16.5	131.6 ±16.2	112.2 ±18.1	106.9 ±18.9	116.2 ±18.7	117.0 ±12.4
ALP (U/L)	86.4±14.7	89.8±16.0	92.4±6.1	85.1±13.9	52.2±14.1	51.9±10.3	54.7±12.8	49.6±8.2
CREA (μmol/L)	41.2±6.0	43.3±3.7	46.6±6.0*	44.7±6.4	43.0±6.3	44.0±4.0	46.6±4.9	38.9±5.8
GLU (mmol/L)	7.88±1.36	7.61±0.90	8.12±1.57	8.02±0.86	6.77±0.79	6.81 ±0.89	6.68±0.90	6.89 ±0.73
Ca (mmol/L)	2.63 ±0.26	2.69±0.25	2.79±0.41	2.77 ±0.33	2.52±0.16	2.59±0.19	2.65±0.24	2.67±0.26
P (mmol/L)	2.83±0.32	3.12±0.31*	3.07±0.28	2.95±0.30	2.18±0.23	1.97±0.26	2.33±0.33	2.24±0.32
TG (mmol/L)	0.63±0.17	0.59 ±0.12	0.63±0.13	0.66±0.11	0.58±0.14	0.52±0.15	0.58±0.16	0.57±0.14
CHOL (mmol/L)	1.85±0.33	1.69±0.29	1.72±0.34	1.69±0.39	2.12 ±0.23	2.09±0.35	1.92±0.19*	1.96±0.50
UREA (mmol/L)	7.49±0.91	7.31±0.85	7.38±1.05	7.93 ±0.83	8.41±1.71	9.02±0.44	8.44±1.58	8.96±1.40
BIL (μmol/L)	0.76 ±0.15	0.79 ±0.11	0.71±0.14	0.66 ±0.13	0.86±0.16	0.80 ±0.16	0.79 ±0.13	0.84±0.10
Na (mmol/L)	139.4±1.3	139.7±1.6	138.7±1.3	139.5±1.7	137.3±2.5	138.0±1.6	138.5±1.1	136.7±2.2
K (mmol/L)	5.51±0.29	5.49±0.39	5.49 ±0.45	5.55±0.71	4.58±0.41	4.61±0.35	4.71±0.41	4.77±0.43
Cl (mmol/L)	105.1±1.4	104.9±1.6	104.9±1.7	103.5±1.0*	103.8±1.8	104.1±1.6	102.9±2.2	103.6±2.0

Adopted from Case et al. (2021); The study was sponsored by AGG. Values were mean±SD.

ALB = albumin; ALP = alkaline phosphatase; ALT = alanine aminotransferase; AST = aspartate aminotransferase; BIL = bilirubin; CHOL = cholesterol; Cl = chloride; CREA = creatinine; GLU = glucose; K = potassium; Na = sodium; TG = triglycerides; TP = total protein; UREA = urea nitrogen.

*P<0.05 vs. control group.

Table 13. Mean Absolute Organ Weights in Male and Female Rats Treated with AGG's Resistant Dextrin

Parameters (g)	Male (mg/kg bw/day)				Female (mg/kg bw/day)			
	Control	1,250	2,500	5,000	Control	1,250	2,500	5,000
Liver	11.33±1.29	11.87±0.94	10.79±1.22	10.72±1.96	7.23±0.73	7.46±0.86	7.62±0.61	7.91±1.15
Kidneys	3.00±0.23	3.26±0.30	2.90±0.24	2.96±0.57	1.78±0.14	1.76±0.16	1.86±0.18	1.85±0.23
Adrenals	0.06±0.02	0.06±0.02	0.06±0.01	0.05±0.02	0.07±0.01	0.07±0.02	0.07±0.02	0.08±0.01
Spleen	0.69±0.08	0.76±0.12	0.72±0.09	0.63±0.09	0.48±0.05	0.52±0.06	0.52±0.07	0.53±0.11
Heart	1.45±0.17	1.40±0.22	1.32±0.10	1.37±0.23	0.90±0.11	0.95±0.09	1.01±0.16	0.95±0.08
Lung	1.69±0.22	1.77±0.26	1.81±0.25	1.62±0.35	1.30±0.13	1.35±0.14	1.49±0.27	1.55±0.31*
Uterus					0.55±0.18	0.64±0.17	0.58±0.15	0.70±0.15
Ovaries					0.15±0.04	0.15±0.06	0.17±0.02	0.17±0.02
Testes	3.29±0.27	3.42±0.46	3.12±0.25	3.21±0.29				
Epididymides	1.31±0.16	1.30±0.09	1.35±0.15	1.25±0.14				
Thymus	0.43±0.09	0.43±0.08	0.47±0.18	0.39±0.09	0.37±0.09	0.37±0.04	0.40±0.12	0.41±0.12
Brain	1.86±0.47	1.93±0.15	1.78±0.25	1.93±0.09	1.69±0.40	1.79±0.14	1.80±0.30	1.82±0.30
Pituitary	0.012 ±0.003	0.012 ±0.002	0.009 ±0.003*	0.011 ±0.003	0.014 ±0.003	0.013 ±0.002	0.015 ±0.004	0.016 ±0.003
Thyroid/ parathyroid	0.036 ±0.008	0.030 ±0.007	0.037 ±0.013	0.037 ±0.013	0.024 ±0.006	0.027 ±0.011	0.030 ±0.009	0.031 ±0.007*

Adopted from Case et al. (2021); The study was sponsored by AGG. Values were mean±SD. *P<0.05 vs. control group.

Table 14. Mean Relative Organ Weights in Male and Female Rats Treated with AGG's Resistant Dextrin

Parameters (%)	Male (mg/kg bw/day)				Female (mg/kg bw/day)			
	Control	1,250	2,500	5,000	Control	1,250	2,500	5,000
Liver	2.31±0.18	2.42±0.23	2.29±0.20	2.23±0.22	2.45±0.21	2.55±0.17	2.57±0.16	2.57±0.32
Kidneys	0.61±0.04	0.66±0.08	0.62±0.05	0.61±0.06	0.61±0.06	0.60±0.03	0.63±0.04	0.60±0.06
Adrenals	0.0115 ±0.0036	0.0118 ±0.0033	0.0128 ±0.0031	0.0112 ±0.0038	0.023 ±0.005	0.024 ±0.008	0.023 ±0.008	0.025 ±0.005
Spleen	0.14±0.01	0.15±0.03	0.15±0.02	0.13±0.01	0.16±0.02	0.18±0.03	0.17±0.03	0.17±0.04
Heart	0.29±0.03	0.29±0.05	0.28±0.02	0.29±0.04	0.31±0.02	0.33±0.02	0.34±0.04	0.31±0.03
Lung	0.35±0.04	0.36±0.06	0.39±0.06	0.34±0.07	0.44±0.05	0.46±0.05	0.50±0.10	0.50±0.09
Uterus					0.19±0.06	0.22±0.07	0.20±0.05	0.23±0.06
Ovaries					0.05±0.02	0.49±0.016	0.06±0.01	0.06±0.01
Testes	0.67±0.04	0.70±0.11	0.66±0.06	0.67±0.08				
Epididymides	0.27±0.03	0.26±0.03	0.29±0.03	0.26±0.03				
Thymus	0.09±0.02	0.09±0.02	0.10±0.04	0.08±0.02	0.13±0.04	0.13±0.02	0.13±0.04	0.13±0.04
Brain	0.38±0.09	0.39±0.03	0.38±0.06	0.41±0.04	0.57±0.12	0.62±0.05	0.61±0.11	0.60±0.12
Pituitary	0.0025 ±0.0005	0.0025 ±0.0004	0.0019 ±0.0006*	0.0023 ±0.0004	0.005 ±0.001	0.005 ±0.001	0.005 ±0.001	0.005 ±0.001
Thyroid/ parathyroid	0.0074 ±0.0017	0.0061 ±0.0015	0.0078 ±0.0029	0.0077 ±0.0027	0.008 ±0.002	0.009 ±0.003	0.010 ±0.003	0.010 ±0.002*

Adopted from Case et al. (2021); The study was sponsored by AGG. Values were mean±SD. *P<0.05 vs. control group.

6.B.3.2. Animal Toxicity Studies of Other Sources of Resistant Dextrins

As shown in Table 10, a subchronic study reported that NOAELs for resistant dextrin were 4,360 mg/kg bw/day and 6,500 mg/kg bw/day in male and female rats, respectively,

Acute Toxicity Studies

Wils et al. (2008) reported that the LD_{50} of wheat starch-based resistant dextrin (Nutriose-FB) was greater than 2 g/kg bw in fasted female rats.

In a book chapter written in English summarizing studies published in Japanese (Hashizume and Okuma, 2009), it was briefly stated that the LD_{50} of resistant maltodextrin (probably corn source) was over 40 g/kg bw in rats.

Subchronic Toxicity Study

In a 90-day, oral subchronic study conducted by Wils et al. (2008), SD rats were administered resistant dextrin (Nutriose FB derived from wheat starch) in their diet at doses of 0, 1.25%, 2.5%, or 5% for 13 weeks. These dietary levels correspond to 1,120, 2,290, and 4,360 mg/kg bw/day, respectively, for males, and 1,610, 3,080, and 6,500 mg/kg bw/day, respectively, for females. No deaths or no significant behavioral changes occurred during the study. The consumption of resistant dextrin did not have any significant effects on body weight or feed or water consumption. No treatment-related abnormalities were observed in blood coagulation and hematology, blood and urine biochemistry, and histopathological examinations. Adverse clinical observations, including ophthalmological observations, were marginal and not considered treatment-related. No treatment-related abnormalities were found on relative or absolute organ weights of rats of either sex, except for the increase in cecum content and cecum mucosa. There was an approximately 15% increase in the absolute empty cecum weight of male and female animals treated with 5% resistant dextrin-wheat. The increase in cecum weight is considered a physiological adaptation seen after the ingestion of indigestible carbohydrates and is not considered a toxicological effect (Leegwater et al., 1974). The NOAELs were established by the highest tested doses: 4,360 mg/kg bw/day in males and 6,500 mg/kg bw/day in females (Table 10).

Conclusions from Animal Toxicity Studies

Two types of AGG's resistant dextrins, derived from corn and tapioca, showed an LD_{50} value higher than 20 g/kg bw and had no significant differences in toxicity profiles. For the purpose of this evaluation, a NOAEL of 5,000 mg/kg bw/day was chosen for resistant dextrin-tapioca from a 90-day subchronic toxicity study.

6.B.4. Human Clinical Studies

6.B.4.1. Digestive Tolerance

The possible side effect associated with excess dietary fiber intake is transitional gastrointestinal discomforts which may not be considered to be of toxicological concern (IOM, 2005). The IOM states that "Although occasional adverse gastrointestinal symptoms were observed with the consumption of dietary and functional fibers, serious chronic adverse effects have not been observed." Since the only possible side effect associated with excessive dietary fiber intake is digestive tolerance, the digestive tolerance was reviewed as a major safety measure of resistant dextrins in this GRN (Table 15).

AGG's Resistant Dextrin

In a randomized, crossover clinical study by Teo and Fairchild (2021), 40 participants (18-75 years; Australia) were randomized and allocated to one of the two study conditions, either AGG's resistant dextrin (tapioca) or control (no resistant dextrin). In the AGG's Resistant Dextrin group, participants consumed resistant dextrin at daily single dose of 10, 30, or 50 g for 7 consecutive days in a dose escalating manner with a 21-day washout period between each of the doses. The resistant dextrin was consumed in a single serving, by addition to a commercially available apple juice beverage. The primary measurement outcomes were the changes in gastrointestinal symptoms and stool characteristics. Secondary outcomes included changes in body anthropometrics (height, weight, body mass index, waist and hip circumference and waist-to-height ratio), vital signs (blood pressure and heart rate), health-related quality of life, and adverse events. Thirty-eight subjects completed the study.

The results showed that the gastrointestinal composite score did not demonstrate a condition by time interaction, although participants in the Resistant Dextrin group had statistically significantly higher average gastrointestinal composite scores compared to the control group. However, the differences were small in magnitude, ranging from 0.04 to 0.1 across the six individual questions (4-point scale). In addition, no significant differences in the frequency or duration of gastrointestinal symptoms were identified between conditions. No adverse events or adverse effects on the measured outcomes were reported by the study participants. The author concluded that resistant dextrin was well tolerated across the doses (10 g/day, 30 g/day, and 50 g/day).

Other Sources of Resistant Dextrins

Marteau et al. (2011) assessed the digestive tolerance of a high dose of resistant dextrin (derived from wheat starch; Nutriose FB10) consumed over the day. In a randomized, double-blind, crossover trial, 12 healthy men (18-50 years) ingested 1 L/day orange juice containing 50 g of either NUTRIOSE®FB10 (derived from wheat) or placebo (maltodextrin) in three equal doses at breakfast, lunch, and a late afternoon meal. Measurement endpoints included bloating, borborygmus, flatulence, nausea feelings, stomach ache, transit and stool consistency that were

evaluated at different times after the first consumption as well as questionnaires on well-being and bowel movement that were completed at 24 and 48 hours. There was no statistical difference between resistant dextrin-wheat and placebo on each criterion. The authors concluded that resistant dextrin-wheat was well tolerated at 50 g divided into three doses during a day.

Baer et al (2014) also reported that consumption of resistant maltodextrin (synonymous with the term 'resistant dextrin'; marketed by Matsutani Chemical Industry; brand name, Fibersol-2) at a daily dose of up to 50 g for 24 days did not result in any adverse effects on stool weight, bowel movement, and gut microbiota in 14 men (35-55 years).

Klosterbuer et al. (2013) reported that a daily dose of 20-25 g dietary fiber from soluble corn fiber (resistant dextrin-corn marketed by Tate & Lyle) was well tolerated in 20 healthy men and women (18-60 years).

Studies discussed in GRN 436

From a short-term human tolerance study, van den Heuvel et al. (2004) reported that resistant dextrin was well tolerated up to 45 g and that higher doses (60 or 80 g) may result in flatulence with no diarrhea. In a study by Pasman et al. (2006), 48 volunteers received resistant dextrin-corn (NUTRIOSE FB 06) at a daily dose of 30 or 45 g for 4 weeks (22.5 g maltodextrin/day as placebo). No serious adverse event occurred. No diarrhea was reported, although there was a tendency for increased flatulence in a dose-dependent manner, but the increase was not substantial compared to those receiving the control (13, 14, and 17 persons reported flatulence during the last 6 days in the placebo, 30 g, and 45 g groups, respectively). Vermorel et al. (2004) demonstrated that ingestion of 100 g of resistant dextrin did not cause severe digestive disorders due to a progressive adaptation and distribution in 6 equal doses per day. However, excessive gas and flatulence were recorded in some subjects after intakes above 50 g/day of resistant dextrin.

Table 15. Human Digestive Tolerance Studies with Large Amounts of Resistant Dextrins

Reference	Subjects	Daily Dose of RD	Source	Control	Duration	Measurements
AGG's Resistant Dextrin						
Teo and Fairchild, 2021	40 healthy subjects (18-75 y)	0, 10, 30, or 50 g FiberSMART® a single dose in apple juice, a dose escalating manner	Tapioca	Apple juice control	1 wk for each dose with 3 wk washout	Gastrointestinal tolerance, changes in body anthropometrics, and vital signs
Other Sources of Resistant Dextrin						
Baer et al, 2014	15 males (35-55 y)	0, 25, or 50 g Fibersol-2	Probably corn	Maltodextrin	24 d with >2 wk washout	Bowel movement; stool wt; excretion of energy and nitrogen; gut microbiota
Klosterbuer et al., 2013	20 healthy men and women (18-60 y)	5 groups: (1) 0; (2)-(5) 20-25 g dietary fiber from soluble corn fiber (SCF; Tate & Lyle); resistant starch (RS); SCF + 5 g pullulan, or RS+ 5 g pullulan	Corn	Maltodextrin	7 d with 3 wk washout	Gastrointestinal tolerance; stool characteristics; gut microbiota
Marteau et al., 2011	12 healthy men (18-50 y)	0, or 50 g NUTRIOSE FB06 (RD-wheat)	Wheat	Maltodextrin in orange juice	8 h with 8 d washout	Digestive tolerance

RD=resistant dextrin.

In the presence of various resistant dextrin preparations, different companies use different terms to describe these ingredients manufactured under the same principle, pyrodextrinization of hydrolyzed starch under acidic heat treatments of overdried starches. The term 'resistant dextrin' is used by AGG and Roquette under the brand names of 'FiberSMART®' and 'NUTRIOSE' (NUTRIOSE FM, derived from corn; NUTRIOSE FB, wheat based), respectively. The term 'resistant maltodextrin' is used by Matsutani Chemical Industry under the brand names of 'Fibersol-2' and 'Pinefibre-C.' The term 'soluble corn fiber' is used by Tate & Lyle under the brand name of 'PROMITOR'.

6.B.4.2. Other Human Clinical Studies

Other human clinical studies investigated the efficacy and safety of resistant dextrins and reported that daily intake of up to 50-60 g for up to 12 weeks did not result in any adverse effects on the measured outcomes (Baer et al, 2014; Nomura et al., 1992). In a book chapter by Hashizume and Okuma (2009), it was stated that resistant dextrin (also called as resistant maltodextrin by Matsutani Chemical Industry under the brand name of Fibersol-2) was made from corn or tapioca starch. This book chapter summarized the study by Nomura et al. (1992) published in Japanese as follows: daily consumption of 60 g resistant dextrin (Fibersol-2) for 12 weeks resulted in no adverse events and no adverse effects on liver function indicator enzymes, serum lipids, plasma glucose concentrations, and erythrocyte counts (Table 16; Nomura et al., 1992). Although Nomura and colleagues did not specify the source of the resistant dextrin preparation used in this study, it is reasonable to expect that both types of resistant dextrins (derived from corn or tapioca) would have similar safety profile.

Table 16. Effects of Resistant Dextrin (60 g/day) on the Safety Parameters NIDDM Patients with Hyperlipidemia

Time (week)	0	2	4	8	12
Fasting plasma glucose (mg/dl)	147±17	112±25	107±7	147±21	103±7a
Cholesterol (mg/dl)	265±10	211±29	209±22a	205±10[b]	209±9b
HDL-Cholesterol (mg/dl)	49±2	45±1	47±3	49±3	40±3b
Triglyceride (mg/dl)	243±34	163±33	134±24a	148±11[a]	176±42
Calcium (meq/l)	4.5±0.3	4.3±0.3	4.5±0.2	4.5±0.2	4.5±0.2
Magnesium (mg/dl)	2.0±0.2	2.0±0.2	2.0±0.2	2.0±0.2	2.0±0.1
Phosphorus (mg/dl)	3.0±0.2	3.3±0.4	3.3±0.5	3.2±0.4	3.4±0.3
Iron (μg/dl)	96±43	98±29	99±18	97±16	88±14
Red blood cell (×104/mm3)	488±31	—	—	—	488±14
AST (IU/l)	22±10	—	—	—	19±4
ALT (IU/l)	22±5	—	—	—	19±4
γ-GTP (IU/l)	69±38	—	—	—	63±54
Lactate dehydrogenase (IU/l)	293±36	—	—	—	311±95

Source: Nomura M, Nakajima Y, Abe H. J Jp. Soc Nut. Food Sci. 1992; 45: 21-25, cited in Hashizume and Okuma, 2009 (a book chapter; page 71).
Source of resistant dextrin was Fibersol-2 derived from corn or tapioca.
Mean±SD, statistical significance: [a] $p<0.05$, [b] $p<0.01$ compared with data at 0 week.
ALT= alanine aminotransferase; AST= aspartate aminotransferase; γ-GTP= gamma-glutamyl transpeptidase; NIDDM= non-insulin dependent diabetes mellitus;

Other human studies evaluated the effects of resistant dextrins on the following parameters (due to an abundance of literature, we have limited our review to the studies with the intervention duration of 3 weeks or longer unless digestive tolerance was tested):

1) Gastrointestinal functions (Abellán-Ruiz et al., 2016; Fastinger et al., 2008; Jakeman et al., 2016; Klosterbuer et al., 2012; Vester Boler et al., 2011; Whisner et al., 2014).

2) Gut microbiota and/or fecal characteristics (Costabile et al., 2016; Fastinger et al., 2008; Holscher et al., 2015; Hooda et al., 2012; Klosterbuer et al., 2012; Ukhanova et al., 2012; Vester Boler et al., 2011; Whisner et al., 2014, 2016),

3) Glucose metabolism and/or metabolic indicators (Abellán-Ruiz et al., 2016; Aliasgharzadh et al., 2015; Farhangi et al., 2018, 2020; Gholizadeh Shamasbi et al., 2019; Hashizume et al., 2012; Hobden et al., 2021; Kitagawa et al., 2020; Nomura et al., 1992),

4) Satiety/energy intake (Guerin-Deremaux et al., 2011a, 2011b; Hashizume et la., 2012; Hobden et al., 2021),

5) Bone strength/mineral absorption (Jakeman et al., 2016; Whisner et al., 2014, 2016),

6) Inflammatory biomarkets (Aliasgharzadh et al., 2015; Farhangi et al., 2017, 2018, 2020),

7) Abdominal fat accumulation (Kitagawa et al., 2020), and

8) Adverse events and /or compliance (Arasu et al., 2021; Abellán-Ruiz et al., 2016; Gholizadeh Shamasbi et al., 2019; Guerin-Deremaux et al., 2011a; Hobden et al., 2021; Jakeman et al., 2016; Kitagawa et al., 2020).

All of these studies listed above reported no adverse effects of resistant dextrins up to 60 g/day on the measured outcomes and are summarized in Table 17.

Summary of Human Clinical Studies

Although resistant dextrin intake at a daily dose of 60 g for 12 weeks did not result in abnormalities in clinical chemistry parameters, gastrointestinal tolerance was considered when evaluating the safety of resistant dextrin. It is summarized that resistant dextrins at daily doses of up to 45 g to 50 g were well tolerated with no major side effects in humans, regardless of their sources.

Table 17. Human Clinical Studies of Other Sources of Resistant Dextrins

Reference	Subjects	Daily Dose of RD	Source	Control	Duration	Measurements
Studies Using Resistant Dextrin Derived from Corn or Tapioca Starch						
Nomura et al, 1992 (cited in Hashizume and Okuma, 2009)	5 subjects with non-insulin-dependent diabetes with hyperlipidemia (age, NA)	60 g (Fibersol-2*; Matsutani Chemical Industry; divided into 3 doses)	(Source*, not specified, but probably corn or tapioca)	No control	12 wk	Serum lipid and plasma glucose concentrations, erythrocyte counts, and liver function indicator enzymes
Hashizume et al., 2012	30 mildly obese subjects with metabolic disorder (ave. age, 60.6 y)	0 or 27 g dietary fiber from Fibersol-2*; divided into 3 doses)		Tea	12 wk	Blood glucose and insulin; satiety/short-term energy intake
Ukhanova et al, 2012	14 healthy males (age, NA)	0, 25, or 50 g (Matsutani Chemical Industry)		Maltodextrin	4 wk	Gut microbiota; fecal bacterial counts, in particular, bifidobacteria
Abellán-Ruiz et al., 2016	66 healthy subjects (18-30 y)	15 g Fibersol-2 (once a day)	Source, not specified but probably corn	Placebo, not specified	21 d	Colonic transit time; defecation characteristics; blood levels of AST, ALT, creatine, and urea; Adverse events
Kitagawa et al., 2020	140 healthy adults (20-65y; mean, 47.1 y)	Placebo or 15 g (Fibersol-2 divided into 3 doses)	Source, not specified but probably corn	Placebo tea beverage	12 wk	Abdominal fat; anthropometric parameters; hematology; blood biochemistry; urinalysis; side effects and adverse events
Studies Using Resistant Dextrin Derived from Corn Starch						

Holscher et al., 2015	20-21 healthy males (20-40 y)	21 g PROMITOR Soluble Corn Fiber 85 (Tate & Lyle), 21 g polydextrose, or no dietary fiber	Corn	Rice crisp bars	3 wk; crossover design with no washout period	Gut microbiota
Hooda et al., 2012						Gut microbiota
Vester Boler et al., 2011						Gastrointestinal tolerance; stool characteristics; fecal fermentative end products
Jakeman et al., 2016	14 healthy postmenopausal women (39.9-79.9 y)	0, 10 or 20 g dietary fiber from PROMITOR Soluble Corn Fiber 85, divided into 2 doses	Corn	Maltodextrin in muffins and drinks	50 d	Bone strength and calcium retention; blood and urine biomarkers of bone turnover; compliance; gastrointestinal symptoms
Whisner et al., 2016	28 adolescents (11-15 y)		Corn		4 wk with a 3 wk washout period	Serum and urine biochemical markers of bone turnover; calcium absorption; fecal SCFA and gut microbiota
Gholizadeh Shamasbi et al., 2019	62 women with polycystic ovary syndrome (18-45 y)	0 or 20 g/d (NUTRIOSE FM 06)	Corn	Maltodextrin in water	3 mo	Metabolic parameters (serum lipid profile, fasting blood glucose, hsCRP); androgen levels; hirsutism and menstrual cycle characteristics; side effects
Fastinger et al., 2008	38 healthy adults (ave. 26.6-28.2 y)	0, 7.5, or 15 g Fibersol-2	Corn	Supplement (maltodextrin)	3 wk	Gastrointestinal tolerance; bowel function, fecal characteristics; gut microbiota; fecal SCFA
Whisner et al., 2014	24 adolescents (12-15 y)	0 or 12 g/d (PROMITOR Soluble Corn	Corn	Fruit snacks (0 or 6 g SCF/serving)	3 wk with a 1 wk washout period	Gastrointestinal symptoms; fractional calcium absorption, calcium

		Fiber 70), divided into two doses				balance and bone biomarker; gut microbiota
Arasu et al., 2021	243 healthy pre-adolescent children (9-11 y)	12 g/d Soluble Corn Fiber ± 600 mg/d calcium; 600 mg/d calcium; placebo	Corn	Placebo (fruit-flavored powder)	1 y	Compliance; study retention rates
Farhangi et al., 2018 Farhangi et al., 2017	55 females with type 2 diabetes mellitus (mean age, 49.2-49.6 y)	0 or 10 g/d NUTRIOSE 06 FM	Corn	Maltodextrin	8 wk	Anthropometry, glycemia indices, blood cell counts and lymphocyte subsets; inflammatory/anti-inflammatory biomarkers; mental health and hypothalamic-pituitary-adrenal axis function
Farhangi et al., 2020	65 females with type 2 diabetes mellitus (30-65 y)	0 or 10 g/d NUTRIOSE 06 FM divided into 2 doses	Corn	Maltodextrin	8 wk	Anthropometry, blood pressure, glycemic indices, lipid profile, inflammatory markers; oxidative stress and antioxidant enzyme activities
Aliasgharzadh et al., 2015	55 women with type 2 diabetes (30-65 y)	0 or 10 g NUTRIOSE 06 FM divided into 2 doses	Corn	Maltodextrin	8 wk	Fasting plasma glucose and insulin, HbA1c, fasting insulin, insulin sensitivity, hs-CRP, TNF-a, IL-6, MDA, endotoxin, changes in body weight and energy intake
Resistant Dextrin Derived from Wheat/Corn						

Guerin-Deremaux et al., 2011a	120 overweight Chinese men (20-35 y)	0 or 34 g NUTRIOSE®, divided into 2 doses	Corn or wheat Starch (not specified)	Maltodextrin in fruit juice	12 wk	Body weight and composition; energy intake; hunger; adverse events
Guérin-Deremaux et al., 2011b	100 healthy overweight adults (35-55 y)	0, 8, 14, 18, or 24 g NUTRIOSE		Orange juice	3 wk	Satiety and hunger feelings
Hobden et al., 2021	20 normal weight and 16 overweight adults (22-55 y)	0 or 14 g/d (NUTRIOSE® FB06)	Wheat	Drinks (placebo, 7 g maltodextrin)	4 wk with 4 wk washout	Anthropometric parameters, blood pressure; satiety; postprandial glucose and insulin; fasting blood glucose, GIP, GLP-1; leptin, IL-6, and TNF-α); energy intake; compliance

GIP=Gastric inhibitory polypeptide; GLP-1= glucagon-like peptide-**1**; HbA1c =Glycated hemoglobin; hs-CRP =high-sensitivity C-reactive protein; IL-6=interleukin-6; MDA=malondialdehyde; RBC=red blood cells; RD=resistant dextrin; TNF-α=tumor necrosis factor alpha.
*The source of Fibersol-2 was specified as corn- or tapioca- in the book chapter by Hashizume and Okuma, 2009 (page 63).

6.B.5. Safety of Raw Materials

The subject of this GRAS determination is FiberSMART®-tapioca, resistant dextrin derived from tapioca starch. As noted in Part 2.A.6., equivalence of corn-, tapioca-, or wheat-derived dextrin is mostly justified from the aspect of its dietary fiber content. Regardless of their source, resistant dextrin powders have a dietary fiber content of 70-90%, depending upon the purification steps involved. Tapioca, sometimes named cassava, is the third most important source of calories in the tropical and subtropical regions of Asia, Africa, and Latin America, after rice and maize (FAO, 2014). Tapioca starch has a long history of safe human consumption. No adverse effects of commercially available tapioca starch were reported.

6.B.6. Potential Adverse Effects

The IOM (2005) has not established UL for dietary fiber by Americans. The UL is defined as a safe upper level for consumption over a lifetime or the highest level of a daily nutrient intake that will most likely present no risk of adverse health effects in almost all individuals in the general population. The states that "Although occasional adverse gastrointestinal symptoms were observed with the consumption of dietary and functional fibers, serious chronic adverse effects have not been observed."

Also, the American Dietetic Association's position paper addressed no serious health hazards related to dietary fiber intakes in the American population (Slavin, 2008).

In addition, FDA has raised the DRV of dietary fiber from 25 g to 28 g for American children aged 4 and older, adults, and pregnant women (FDA, 2016a).

Taken together, it is not expected that excessive dietary fiber intake, including resistant dextrins, would result in serious chronic adverse effects.

6.D. Safety Determination

The following safety evaluation fully considers the composition, intake, and nutritional, microbiological, and toxicological properties of resistant dextrins as well as appropriate corroborative data.

1. AGG's resistant dextrin (derived from tapioca) is manufactured under current Good Manufacturing Practice (cGMP) using common food industry materials and processes.

2. Analytical data from multiple lots indicate that AGG's resistant dextrin comply reliably with established food-grade product specifications.

3. AGG's resistant dextrin is intended to be used in conventional foods and beverages, excluding infant formula, and meat, egg, and poultry products, in a manner similar to many other dietary fiber ingredients. AGG's resistant dextrin is intended to be used in the following food categories at approximately 1.2 to 10 g/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 including processed dried fruits; (14) shelf-stable desserts; (15) snacks and crackers; (16) dry beverage powder; and (17) nutrition bars.

4. The U.S. per capita mean intake from all the selected food categories is 14.4 g/day and the corresponding 90^{th} percentile intake is 26.5 g/day. FDA has established a DRV for dietary fiber as 28 g/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 (28 g/person/day). In reality, Americans' mean per capita dietary fiber intake is only 16.2 g per day or 58% of the recommended intakes, indicating that the actual intake levels are far below theoretical, optimistic EDI values estimated in this GRAS determination. It is noteworthy that IOM has not established an UL for dietary fiber.

5. The EDI values are based on the assumption that AGG's resistant dextrin will replace currently marketed resistant dextrin and/or dietary fiber ingredients. Thus, cumulative exposures are not expected to change.

6. The LD_{50} value of AGG's resistant dextrin (tapioca), was determined to be higher than 20 g/kg bw in rats, indicating that the substance belongs to the groups that have the lowest toxicity rating. Bacterial reverse mutation assay showed that AGG's resistant dextrin (both corn and tapioca) was not mutagenic. In addition, literature searches did not identify safety or toxicity concerns related to resistant dextrins, regardless of their sources. A subchronic study reported that the NOAELs for AGG's resistant dextrin was 5,000 mg/kg bw/day in both male and female rats. The NOAEL values were comparable to other sources of resistant dextrin (derived from wheat): 4,360 mg/kg bw/day and 6,500 mg/kg bw/day in male and female rats, respectively.

7. In a human study, AGG's resistant dextrin was well tolerated at daily doses up to 50 g. This gastrointestinal tolerance level is comparable with those found in other human studies.

8. In a previous GRN (GRN 436) to the FDA, the safety of resistant dextrins was also established in toxicological studies in animals and in mutagenicity studies, and is further supported by clinical studies in humans.

6.E. Conclusions and General Recognition of the Safety of Resistant Dextrin

AGG claims that the use of its resistant dextrin in foods, as described in Parts 2 through 7 of this GRAS document, is not subject to premarket approval requirements of the FD&C Act based on its conclusion that the substance is GRAS under the conditions of its intended use.

AGG intends to market its resistant dextrin ingredient, FiberSMART®, as a food ingredient in the U.S. for use in selected conventional foods.

Two other sources of resistant dextrin (derived from corn and wheat) have been evaluated by the FDA in the past few years for proposed incorporation of resistant dextrin ingredients in foods. A relevant U.S. GRAS notification includes GRN 436 (FDA, 2013). This GRN provided information or clinical study data that supported the safety of the proposed resistant dextrin products for use as a food ingredient. In all the studies summarized in the notification, there were no significant adverse effects/events or tolerance issues attributable to resistant dextrin. Because this safety evaluation was based on generally available and widely accepted data and information, it satisfies the so-called "common knowledge" element of a GRAS determination.

In addition, the intended uses of AGG's resistant dextrin have been determined to be safe though scientific procedures as set forth in 21 CFR §170.3(b), thus satisfying the so-called "technical" element of the GRAS determination. The specifications of the proposed GRAS substance, AGG's resistant dextrin, are substantially equivalent to those that have received a FDA 'no question' letter.

The AGG's resistant dextrin derived from tapioca starch, that is the subject of this GRAS determination, contains over 80% and 60% of dietary fiber in the powder and syrup forms, respectively. AGG's resistant dextrin is manufactured consistently with cGMP for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade. Literature searches did not identify safety or toxicity concerns related to resistant dextrins. Toxicity studies of AGG's resistant dextrin include bacterial reverse mutation study, and acute and subchronic toxicity in rats. In these reports, no evidence of toxicity was noted at doses up to 5,000 mg/kg bw/day, the highest dose level tested. The publicly available scientific literature on the consumption and the safety of resistant dextrin in human clinical studies is extensive and sufficient to support the safety and GRAS status of the proposed resistant dextrin ingredient. In addition, the IOM recommends that Americans should

increase their dietary fiber intakes to 14 g/1,000 kcal intake. In line with the IOM recommendation, the FDA has raised the DRV of dietary fiber from 25 to 28 g person per day.

AGG further concluded that the intended use of its resistant dextrin (tapioca) is GRAS based on scientific procedures, and that experts qualified to assess the safety of foods and food additives would concur with this conclusion.

6.F. Discussion of Information Inconsistent with GRAS Determination

We are not aware of information that would be inconsistent with a finding that the proposed use of resistant dextrin, meeting appropriate specifications and used according to cGMP, is GRAS.

PART 7. LIST OF DATA AND SUPPORTING INFORMATION

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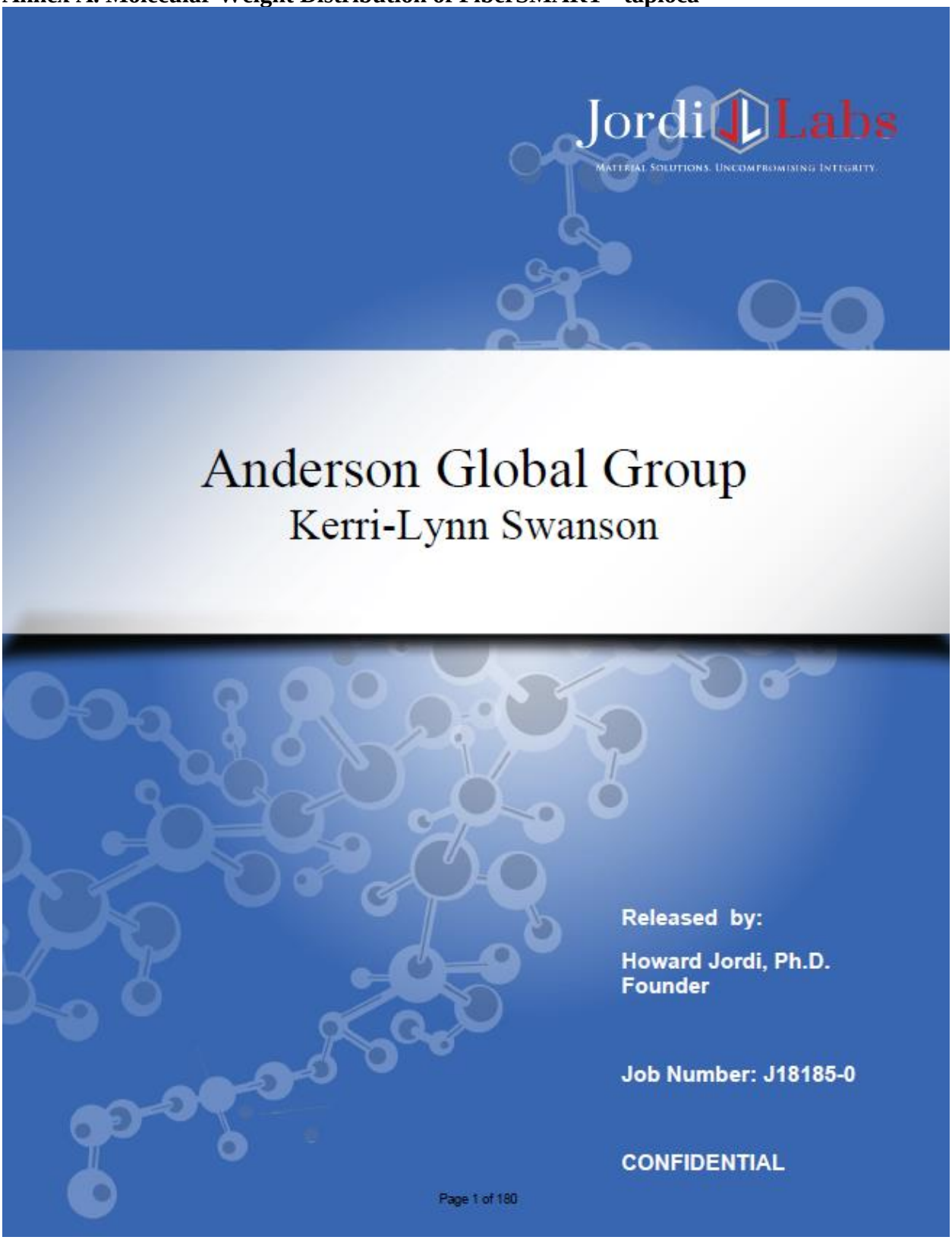
7.B. References That Are Not Generally Available

Not applicable.

Annex A. Molecular Weight Distribution of FiberSMART®-tapioca



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December 16, 2021

Kerri-Lynn Swanson
Anderson Global Group
2030 Main Street, Suite 430
Irvine, CA 92614

P: 949-502-4770
E: kerrilynns@andersonglobalgroup.com

Dear Kerri-Lynn,

Please find enclosed the test results for your polysaccharide syrup sample described as:

1. *FiberSMART Soluble Tapioca Fiber Powder, Item Code: 60750, Lot Number: 20210703027 (referred to as Lot: 20210703027)*
2. *FiberSMART Soluble Tapioca Fiber Powder, Item Code: 60750, Lot Number: 20200622037 (referred to as Lot: 20200622037)*

The following test was performed:

1. Standardized Gel Permeation Chromatography (GPC)

Objective

Two (2) samples were submitted for analysis, similar to **J12334** using the conditions depicted in **Figure 1**. It was explained that the samples were derived from starch which had gone through an enzymatic process in order to form dextrin. It was recognized that some of the samples were produced from corn starch, while other samples originated from tapioca starch. It was communicated that you were interested in replicating the results in J12334, which include the molecular weight distribution and degree of polymerization in the sample for FDA GRAS[1] filing. ***The goal of this analysis was to determine the relative molecular weight distribution and percentage solids of chains with varying degree of polymerization (DP) using the methodology outlined in J12334, for FDA GRAS filing.***

[1] Generally Recognized as Safe

Solvent	Water (0.1 M $NaNO_3$)
Flow Rate	0.7 mL/min
Injection Volume	100 µL
Column Temperature	35 °C
Concentration	2.5 mg/mL for sample, 0.5 mg/mL for standards
Column	Aquagel-OH Mixed M and Aquagel-OH 20
Run Time	40 minutes
Sample Prep Conditions	~5 hours at ambient temperature with orbital shaking
Standards	Poly(saccharide): 642k, 337k, 194k, 47.1k, 21.1k, 9.6k, 6.2k, 667 and 180 Da

Figure 1. J12334 conditions which were replicated in this report

Summary of Results

Samples exhibit similar molecular weight distributions, all with low M_w values of approximately 767 Da. Molecular weight averages and dispersity values are summarized in **Table 1**. The weight percentages for consecutive degree of polymerization (DP) integers have been determined for each sample. 97.5% total weight was achieved by DP36, and calculated values have been reported up DP37 (**Table 2**).

Individual Test Results

A summary of the individual test results is provided below. All accompanying data, including spectra, has been included in the data section of this report.

GPC

GPC Background

A polymer is a large molecule which is formed using a repeating subunit. A polymeric sample does not have a single molecular weight but rather a range of values. Thus to describe the range of molecular weights of a polymer, a molecular weight distribution curve displaying the fraction of sample with a given molecular weight is commonly used. The molecular weight distribution curve is therefore a graphical representation of the range of the molecular weights of the sample. The width of the distribution curve reflects the polydispersity of the sample, the narrower the distribution, the lower the polydispersity.

To describe the molecular weight distribution of a polymer numerically, three different molecular weight averages are commonly used. These are the number average molecular weight (M_n), the weight average molecular weight (M_w), and the Z average molecular weight (M_z). M_n provides information about the lowest molecular weight portion of the sample. M_w is the average closest to the center of the curve and M_z represents the highest molecular weight portion of the sample. They are calculated according to the equations below, where M_i is the molecular weight, N_i is the fraction of the molecular with a molecular weight of M_i.

$$M_n = \frac{\sum M_i N_i}{\sum N_i} \quad \text{(Number Average Molecular Weight)}$$

$$M_w = \frac{\sum M_i^2 N_i}{\sum M_i N_i} \quad \text{(Weight Average Molecular Weight)}$$

$$M_z = \frac{\sum M_i^3 N_i}{\sum M_i^2 N_i} \quad \text{(Z} - \text{Average Molecular Weight)}$$

Therefore, given all M_i and N_i for a polymer sample, a molecular weight distribution curve can be derived.

Accuracy

Standardized GPC calculates molecular weight values through a comparison between the retention times of samples of *unknown* molecular weight with those of standards of *known* molecular weight. This method assumes that if two molecules are of the same size in solution then they are the same molecular weight. The accuracy of this assumption is directly dependent upon the similarity between the hydrodynamic volume of the standards and that of the sample for a given molecular weight. Factors which are important in determining the hydrodynamic volume of a polymer include the polarity and rigidity of a polymer, as well as the presence of charged functional groups incorporated into the polymer. It is therefore desired to keep the chemistry of the standards (charge, polarity, chain stiffness) as similar as possible to that of the samples.

In addition, it is assumed in standardized GPC that the only separation mechanism present is separation by size. Other factors such as sample-column or sample-sample interactions can result in non-sized based separation effects. Tetra-detection GPC can be used to confirm the absence of these effects and serves as an excellent way to validate a standardized GPC method. The accuracy of standardized GPC is generally expected to be within 10% of the accurate value when a purely sized based separation is obtained and the hydrodynamic volumes of the standards correlate well with those for the sample. In comparison, tetradetection GPC typically has accuracy on the order of 5% and makes no similar assumptions about sample hydrodynamic volume or separation by size.

Sample Preparation

Samples were dissolved in eluent for approximately 5 hours at room temperature with gentle agitation.

Results

The calculated molecular weight averages for the samples (M_n, M_w, M_z) as well as the dispersity values (PDI) are presented in **Table 1**. The refractive index chromatograms, cumulative weight fraction curves and the molecular weight distributions for the samples are presented in **Figure 3** through **Figure 5**, respectively. A calibration curve and chromatographic overlay of the standards are included in the data section of this report.

Discussion of Results

Samples exhibit similar molecular weight distributions, all with low M_w values of approximately 767 Da. Samples were integrated until the observed solvent affect (**Figure 2**). Molecular weight averages and dispersity values are summarized in **Table 1**.

The weight percentages for consecutive degree of polymerization (DP) integers have been determined for each sample, until a total cumulative sample weight of greater than 97.5% had been achieved. Molecular weight values taken for each degree of polymerization are based on glucose (DP1), with each consecutive DP adding an additional glucose unit (180.16 Da) with the removal of water. For example, for DP3 (maltotriose) 180.16 Da is added onto 342.30 Da (DP2, maltose) and 18.02 Da is subtracted for the removal of water, yielding 504.44 Da (D4).

97.5% total weight was achieved by DP36, and calculated values have been reported up DP37 (**Table 2**). Cumulative weight plots were used in the calculations, and are presented separately in the data section of this report.

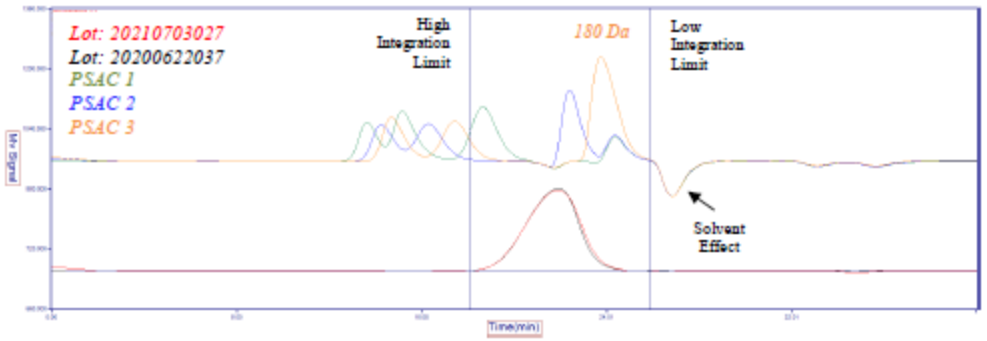


Figure 2. Overlay of the two samples with standards, highlighting the integration limits

Table 1
Average Molecular Weight
Relative to Poly(saccharide) Standards

Sample ID	Run	M_n (Da)	Avg. (Da)	M_w (Da)	Avg. (Da)	M_z (Da)	Avg. (Da)	M_w/M_n	Avg.	Avg. DP
Lot: 20210703027	1	734	749	1,711	1,717	3,053	3,061	2.33	2.29	10.48
	2	764		1,722		3,068		2.25		
Lot: 20200622037	1	820	786	1,732	1,746	2,979	3,010	2.11	2.23	10.66
	2	751		1,760		3,041		2.34		

$$Avg.DP = \frac{(Avg.Mw - 18.02\ Da)}{162.14\ Da}$$

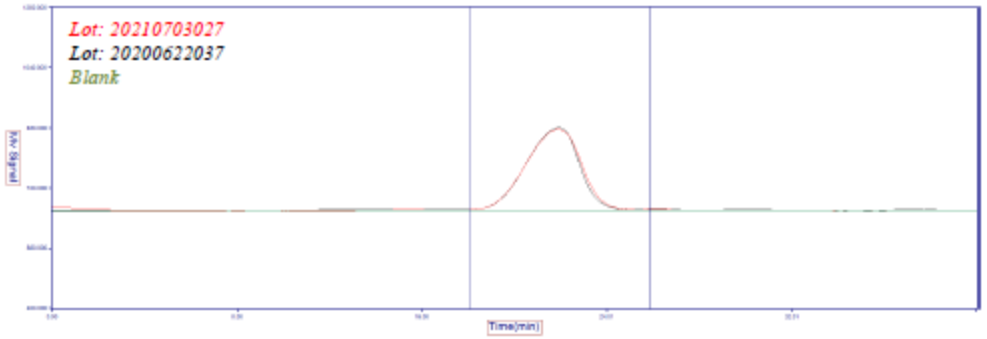


Figure 3. Normalized overlay of refractive index (RI) chromatograms of the samples and blank with integration limits

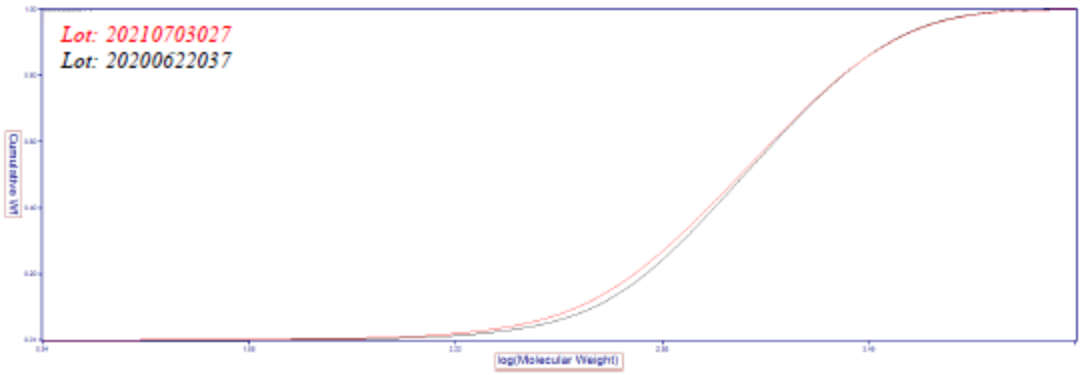


Figure 4. Overlay of cumulative weight fraction curves for the samples

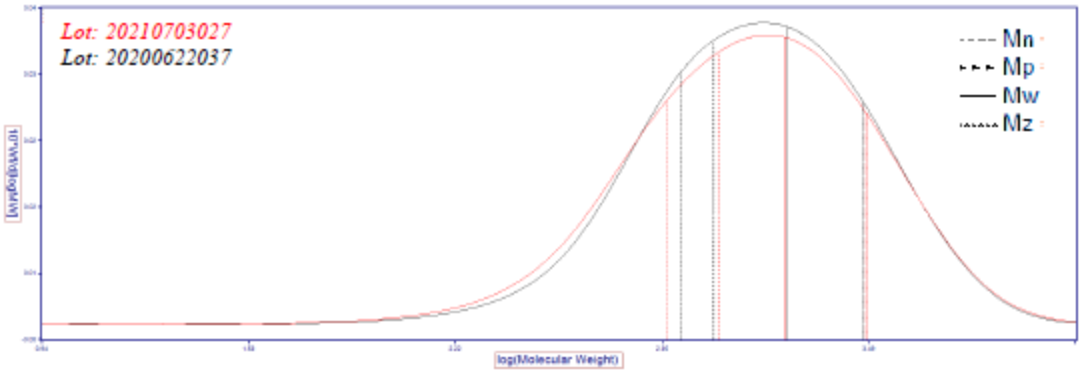


Figure 5. Overlay of molecular weight distribution curves for the sample

Table 2.
Solid Percentages for each DP of Samples Relative to Pullulan Standards

Degree (DP) of Polymerization	Run #	M_w (g/mol)	*Lot: 20210703027*				*Lot: 20200622037*			
			Cumulative Weight %	Average	% of Solids for DP	Average	Cumulative Weight %	Average	% of Solids for DP	Average
DP1 *Glucose*	1	180.16	2.31	2.24	2.31	2.24	1.65	1.79	1.65	1.79
	2		2.17		2.17		1.93		1.93	
DP2 *Maltose*	1	342.30	7.78	7.67	5.47	5.43	6.00	6.06	4.35	4.27
	2		7.55		5.38		6.11		4.18	
DP3 *Maltotriose*	1	504.44	15.64	15.49	10.17	10.07	13.07	12.98	8.72	8.72
	2		15.34		9.96		12.89		8.71	
DP4	1	666.58	24.29	24.12	14.12	14.06	21.64	21.42	12.92	12.70
	2		23.95		13.99		21.19		12.48	
DP5	1	828.72	32.52	32.35	18.40	18.29	30.21	29.91	17.29	17.21
	2		32.17		18.18		29.61		17.13	
DP6	1	990.86	39.94	39.77	21.54	21.48	38.05	37.72	20.76	20.51
	2		39.59		21.41		37.38		20.25	
DP7	1	1,153.00	46.52	46.35	24.98	24.88	45.00	44.65	24.24	24.15
	2		46.18		24.77		44.30		24.05	
DP8	1	1,315.14	52.34	52.18	27.36	27.31	51.12	50.76	26.88	26.61
	2		52.02		27.25		50.39		26.34	
DP9	1	1,477.28	57.50	57.35	30.14	30.04	56.50	56.14	29.62	29.53
	2		57.19		29.94		55.77		29.43	
DP10	1	1,639.42	62.06	61.92	31.92	31.88	61.24	60.89	31.62	31.36
	2		61.77		31.83		60.53		31.10	
DP11	1	1,801.56	66.10	65.97	34.18	34.09	65.45	65.10	33.83	33.74
	2		65.83		34.00		64.74		33.64	
DP12	1	1,963.70	69.69	69.57	35.51	35.48	69.17	68.83	35.34	35.10
	2		69.44		35.44		68.49		34.85	
DP13	1	2,125.84	72.88	72.76	37.37	37.29	72.48	72.15	37.14	37.06
	2		72.64		37.20		71.82		36.97	
DP14	1	2,287.98	75.72	75.61	38.35	38.32	75.42	75.10	38.28	38.05
	2		75.49		38.29		74.78		37.81	
DP15	1	2,450.12	78.24	78.14	39.89	39.82	78.04	77.73	39.76	39.69
	2		78.03		39.74		77.42		39.61	
DP16	1	2,612.26	80.49	80.40	40.60	40.58	80.37	80.08	40.61	40.39
	2		80.30		40.56		79.78		40.17	

Table 2.
Solid Percentages for each DP of Samples Relative to Pullulan Standards

Degree (DP) of Polymerization	Run #	M_w (g/mol)	*Lot: 20210703027*				*Lot: 20200622037*			
			Cumulative Weight %	Average	% of Solids for DP	Average	Cumulative Weight %	Average	% of Solids for DP	Average
DP17	1	2,774.40	82.50	82.41	41.90	41.83	82.44	82.16	41.83	41.77
	2		82.32		41.76		81.88		41.71	
DP18	1	2,936.54	84.29	84.21	42.39	42.38	84.29	84.02	42.46	42.25
	2		84.12		42.36		83.75		42.04	
DP19	1	3,098.68	85.88	85.81	43.49	43.43	85.93	85.68	43.47	43.43
	2		85.73		43.37		85.43		43.39	
DP20	1	3,260.82	87.31	87.24	43.82	43.81	87.40	87.16	43.93	43.73
	2		87.17		43.80		86.92		43.53	
DP21	1	3,422.96	88.59	88.53	44.77	44.72	88.71	88.48	44.78	44.75
	2		88.46		44.66		88.25		44.72	
DP22	1	3,585.10	89.73	89.67	44.96	44.96	89.88	89.67	45.10	44.92
	2		89.61		44.95		89.45		44.73	
DP23	1	3,747.24	90.76	90.71	45.80	45.75	90.92	90.72	45.82	45.80
	2		90.65		45.70		90.51		45.78	
DP24	1	3,909.38	91.67	91.62	45.87	45.87	91.85	91.66	46.03	45.86
	2		91.57		45.87		91.47		45.69	
DP25	1	4,071.52	92.49	92.45	46.62	46.58	92.67	92.50	46.64	46.64
	2		92.40		46.53		92.32		46.63	
DP26	1	4,233.66	93.23	93.19	46.61	46.62	93.42	93.25	46.78	46.62
	2		93.15		46.62		93.08		46.45	
DP27	1	4,395.80	93.89	93.86	47.28	47.24	94.08	93.92	47.30	47.31
	2		93.82		47.20		93.76		47.31	
DP28	1	4,557.94	94.49	94.46	47.21	47.22	94.67	94.53	47.37	47.22
	2		94.42		47.22		94.38		47.07	
DP29	1	4,720.08	95.02	94.99	47.81	47.78	95.21	95.07	47.84	47.85
	2		94.96		47.74		94.93		47.86	
DP30	1	4,882.22	95.50	95.47	47.69	47.70	95.68	95.55	47.84	47.70
	2		95.44		47.70		95.42		47.56	
DP31	1	5,044.36	95.93	95.91	48.24	48.21	96.11	95.99	48.27	48.29
	2		95.88		48.18		95.87		48.31	
DP32	1	5,206.50	96.32	96.30	48.08	48.09	96.50	96.39	48.23	48.10
	2		96.27		48.09		96.27		47.96	

Table 2.
Solid Percentages for each DP of Samples Relative to Pullulan Standards

Degree (DP) of Polymerization	Run #	M_w (g/mol)	*Lot: 20210703027*				*Lot: 20200622037*			
			Cumulative Weight %	Average	% of Solids for DP	Average	Cumulative Weight %	Average	% of Solids for DP	Average
DP33	1	5,368.64	96.67	96.65	48.59	48.56	96.85	96.74	48.62	48.65
	2		96.62		48.53		96.63		48.67	
DP34	1	5,530.78	96.99	96.97	48.40	48.41	97.16	97.06	48.54	48.41
	2		96.94		48.41		96.95		48.28	
DP35	1	5,692.92	97.27	97.25	48.87	48.85	97.44	97.34	48.90	48.93
	2		97.23		48.82		97.24		48.96	
DP36	1	5,855.06	97.53	97.51	48.66	48.67	97.69	97.60	48.79	48.67
	2		97.49		48.67		97.51		48.55	
DP37	1	6,017.20	97.76	97.74	49.10	49.08	97.92	97.84	49.13	49.17
	2		97.72		49.05		97.75		49.20	

Pages 11-180 GPL data

Annex B. Glycosidic Linkage Characterization of FiberSMART®-tapioca

Final Report

TO :	Steve Prancevic, Anderson Advanced Ingredients
CC :	
FROM :	Anton Terekhov
DATE :	October 17, 2021
SUBJECT :	Linkage and anomeric configuration analysis

1

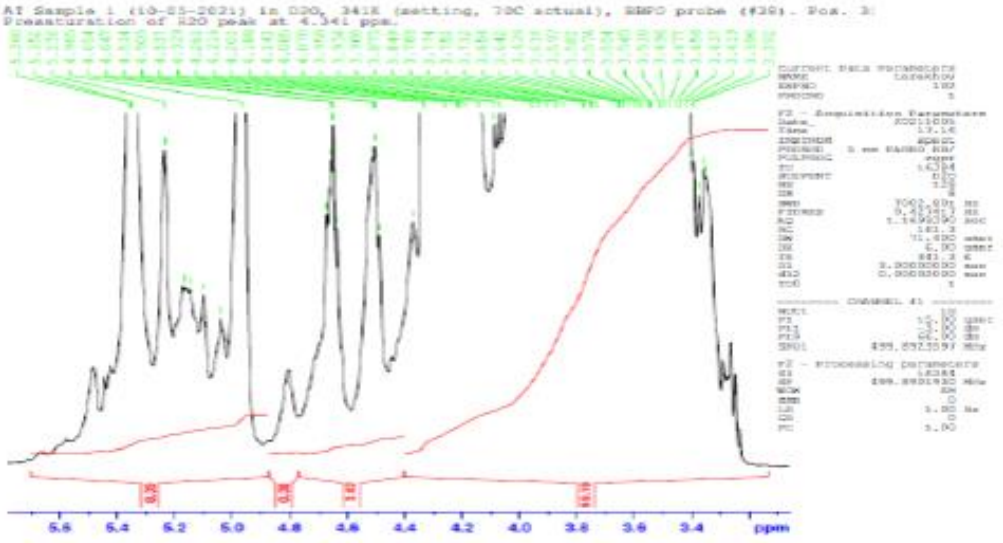
WHISTLER CENTER for Carbohydrate Research — PURDUE UNIVERSITY

Results:

Table 1. Linkages

Linkages	% Linkage
T-Glc	52.3±0.2
1,3-Glc	7.3±0.2
1,2-Glc	4.2±0.1
1,6-Glc	18.4±0.2
1,4-Glc	12.6±0.0
1,3,4-Glc	1.0±0.1
1,2,3-Glc	0.3±0.0
1,2,4-Glc	0.6±0.0
1,3,6-Glc	1.1±0.1
1,4,6-Glc	2.1±0.0

Chromatogram 1. NMR



α-Glc (5.6 - 4.9 ppm) β-Glc (4.9 – 4.4 ppm)

2

Table 2. NMR – anomeric configuration

% α-Glc	% β-Glc
67.7	32.3

Annex C. Certificate of Analysis (COAs) for Tapioca Starch (Raw Material)

Summary of Mycotoxin, Bromide, DTCs, and Pesticides Present in Tapioca Starch (Raw Material)

Parameters	Lot Number		
	1210720	20170226	20170320
Mycotoxin, ng/g			
Aflatoxin, ng/g			
Aflatoxin B1	<1.3	<0.500	<0.500
Aflatoxin B2	<1.2	<0.500	<0.500
Aflatoxin G1	<1.1	<0.500	<0.500
Aflatoxin G2	<1.6	<0.500	<0.500
Fumonosin, ug/kg			
Fumonosin B1	<0.1		
Fumonosin B2	<0.1		
Fumonosin B3	<0.1		
Ochratoxin A, ug/kg	<1.1		
Vomitoxin, mg/kg			
Deoxynivalenol	<0.1		
Acetyldeoxynivalenol	<0.1		
Bromide, mg/kg	<125	<125	<125
Dithiocarbamates, mg/kg	<2	<2	<2
USP 561 Pesticides, mg/kg			
Acephate	<0.1	<0.1	<0.1
Alachlor	<0.05	<0.05	<0.05
Aldrin and dieldrin	<0.05	<0.05	<0.05
Azinphos-ethyl	<0.1	<0.1	<0.1
Azinphos-methyl	<1	<1	<1
Bromophos-ethyl	<0.05	<0.05	<0.05
Bromophos-methyl	<0.05	<0.05	<0.05
Bromopropylate	<3	<3	<3
Chlordane (sum)	<0.05	<0.05	<0.05
Chlorfenvinphos	<0.5	<0.5	<0.5
Chloropyrifos	<0.2	<0.2	<0.2
Chlorpyrifos-methyl	<0.1	<0.1	<0.1
Chlorthal-dimethyl	<0.01	<0.01	<0.01
Cyfluthrin I-IV	<0.1	<0.1	<0.1
Cyhalothrin, lambda-	<1	<1	<1
Cypermethrin I-IV	<1	<1	<1
DDT (sum)	<1	<1	<1
Deltamethrin	<0.5	<0.5	<0.5
Diazinon	<0.5	<0.5	<0.5

Dichlofluanid	<0.1	<0.1	<0.1
Dichlorvos	<1	<1	<1
Dicofol	<0.5	<0.5	<0.5
Dimethoate and omethoate	<0.1	<0.1	<0.1
Endosulfan	<3	<3	<3
Endrin	<0.05	<0.05	<0.05
Ethion	<2	<2	<2
Etrimphos	<0.05	<0.05	<0.05
Fenchlorphos (sum)	<0.1	<0.1	<0.1
Fenitrothion	<0.5	<0.5	<0.5
Fenpropathrin	<0.03	<0.03	<0.03
Fensulfothion	<0.05	<0.05	<0.05
Fenthion	<0.05	<0.05	<0.05
Fenvalerate, I & II	<1.5	<1.5	<1.5
Flucythrinate, I & II	<0.05	<0.05	<0.05
Fluvalinate, tau-, I & II	<0.05	<0.05	<0.05
Fonofos	<0.05	<0.05	<0.05
Heptachlor (sum)	<0.05	<0.05	<0.05
Hexachlorobenzene (HCB)	<0.1	<0.1	<0.1
Hexachlorocyclohexane isomers (other than gamma)	<0.3	<0.3	<0.3
Lindane (gamma HCH)	<0.6	<0.6	<0.6
Malathion and malaoxon (sum of)	<1	<1	<1
Mecarbam	<0.05	<0.05	<0.05
Methacriphos	<0.05	<0.05	<0.05
Methamidophos	<0.05	<0.05	<0.05
Methidathion	<0.2	<0.2	<0.2
Methoxychlor	<0.05	<0.05	<0.05
Mirex	<0.01	<0.01	<0.01
Monocrotphos	<0.1	<0.1	<0.1
Parathion-ethyl and paraoxon-ethyl (sum of)	<0.5	<0.5	<0.5
Parathion-methyl and paraoxon-methyl (sum of)	<0.2	<0.2	<0.2
Pendimethalin	<0.1	<0.1	<0.1
Pentachloranisol	<0.01	<0.01	<0.01
Permethrin (sum of isomers)	<1	<1	<1
Phosalone	<0.1	<0.1	<0.1
Phosmet	<0.05	<0.05	<0.05
Piperonyl butoxide	<3	<3	<3
Pirimiphos-ethyl	<0.05	<0.05	<0.05
Pirimiphos-methyl (sum)	<4	<4	<4
Procymidone	<0.1	<0.1	<0.1
Profenophos	<0.1	<0.1	<0.1

Prothiophos	<0.05	<0.05	<0.05
Pyrethrum (total isomers)	<3	<3	<3
Quinalphos	<0.05	<0.05	<0.05
Quintozene (sum)	<1	<1	<1
S-421	<0.02	<0.02	<0.02
Tecnazene	<0.05	<0.05	<0.05
Tetradifon	<0.3	<0.3	<0.3
Vinclozolin	<0.4	<0.4	<0.4

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ANDERSON GLOBAL GROUP, LLC

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2030 Main Street
Suite 150
Irvine, CA 92614

ANALYTICAL REPORT

AR-21-QR-032037-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Eurofins Sample Code: 111-2021-10180037
Client Sample Code: RGE1210717
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt: acceptable, 22°C
Sample Reference:

QA0SW - Dithiocarbamates by LC-MS/MS per USP <561>	Reference	Accreditation	Completed	Sub
	Anal Bioanal Chem, 2008,392(5), 969-978.Modified.	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Dithiocarbamates (as CS2)	<2.00 mg/kg

QA0SY - Bromide, inorganic (GC-MS) <USP 561>	Reference	Accreditation	Completed	Sub
	EURL-SRM, Bromine Containing Fumigants	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Total Inorganic Bromide	<125 mg/kg

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Acephate	<0.1 mg/kg
Alachlor	<0.05 mg/kg
Aldrin and dieldrin (sum of)	<0.05 mg/kg
Azinphos-ethyl	<0.1 mg/kg
Azinphos-methyl	<1 mg/kg
Bromophos-ethyl	<0.05 mg/kg
Bromophos-methyl	<0.05 mg/kg
Bromopropylate	<3 mg/kg
Chlordane (sum)	<0.05 mg/kg
Chlorfenvinphos	<0.5 mg/kg
Chlorpyrifos	<0.2 mg/kg
Chlorpyrifos-methyl	<0.1 mg/kg
Chlorthal-dimethyl	<0.01 mg/kg
Cyfluthrin I-IV	<0.1 mg/kg

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QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Cyhalothrin, lambda-	<1 mg/kg
Cypermethrin I-IV	<1 mg/kg
DDT (sum)	<1.0 mg/kg
Deltamethrin	<0.5 mg/kg
Diazinon	<0.5 mg/kg
Dichlofluanid	<0.1 mg/kg
Dichlorvos	<1 mg/kg
Dicofol, o,p' & p,p'-	<0.5 mg/kg
Dimethoate and omethoate (sum of)	<0.1 mg/kg
Endosulfan (sum)	<3.0 mg/kg
Endrin	<0.05 mg/kg
Ethion	<2 mg/kg
Etrimfos	<0.05 mg/kg
Fenchlorophos (sum)	<0.1 mg/kg
Fenitrothion	<0.5 mg/kg
Fenpropathrin	<0.03 mg/kg
Fensulfothion (sum)	<0.05 mg/kg
Fenthion (sum)	<0.05 mg/kg
Fenvalerate I&II	<1.5 mg/kg
Flucythrinate I&II	<0.05 mg/kg
Fluvalinate, tau- I&II	<0.05 mg/kg
Fonofos	<0.05 mg/kg
Heptachlor (sum)	<0.05 mg/kg
Hexachlorobenzene (HCB)	<0.1 mg/kg
Hexachlorocyclohexane isomers (other than gamma)	<0.3 mg/kg
Lindane (gamma-HCH)	<0.6 mg/kg
Malathion and malaoxon (sum of)	<1 mg/kg
Mecarbam	<0.05 mg/kg
Methacrifos	<0.05 mg/kg
Methamidophos	<0.05 mg/kg
Methidathion	<0.2 mg/kg
Methoxychlor	<0.05 mg/kg
Mirex	<0.01 mg/kg

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Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt: acceptable, 22°C
Sample Reference:

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Monocrotophos	<0.1 mg/kg
Parathion-ethyl and paraoxon-ethyl (sum of)	<0.5 mg/kg
Parathion-methyl and paraoxon-methyl (sum of)	<0.2 mg/kg
Pendimethalin	<0.1 mg/kg
Pentachloranisole	<0.01 mg/kg
Permethrin (sum of isomers)	<1 mg/kg
Phosalone	<0.1 mg/kg
Phosmet	<0.05 mg/kg
Piperonyl butoxide	<3 mg/kg
Pirimiphos-ethyl	<0.05 mg/kg
Pirimiphos-methyl (sum)	<4 mg/kg
Procymidone	<0.1 mg/kg
Profenofos	<0.1 mg/kg
Prothiofos	<0.05 mg/kg
Pyrethrum (total isomers)	<3 mg/kg
Quinalphos	<0.05 mg/kg
Quintozene (sum)	<1 mg/kg
S 421	<0.02 mg/kg
Tecnazene	<0.05 mg/kg
Tetradifon	<0.3 mg/kg
Vinclozolin	<0.4 mg/kg

QA0T0 - Standard Addition Confirmation <USP561>	Reference	Accreditation	Completed	Sub
	No Reference	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Standard Addition Confirmation	not required

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, LA

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Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Respectfully Submitted,

Viridiana Castro
Assistant Laboratory Manager

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ANALYTICAL REPORT

AR-21-QR-032038-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Eurofins Sample Code: 111-2021-10180038
Client Sample Code: RGE1210720
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt: acceptable, 22°C
Sample Reference:

QA0SW - Dithiocarbamates by LC-MS/MS per USP <561>	Reference	Accreditation	Completed	Sub
	Anal Bioanal Chem, 2008,392(5), 969-978.Modified.	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Dithiocarbamates (as CS2)	<2.00 mg/kg

QA0SY - Bromide, inorganic (GC-MS) <USP 561>	Reference	Accreditation	Completed	Sub
	EURL-SRM, Bromine Containing Fumigants	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Total Inorganic Bromide	<125 mg/kg

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Acephate	<0.1 mg/kg
Alachlor	<0.05 mg/kg
Aldrin and dieldrin (sum of)	<0.05 mg/kg
Azinphos-ethyl	<0.1 mg/kg
Azinphos-methyl	<1 mg/kg
Bromophos-ethyl	<0.05 mg/kg
Bromophos-methyl	<0.05 mg/kg
Bromopropylate	<3 mg/kg
Chlordane (sum)	<0.05 mg/kg
Chlorfenvinphos	<0.5 mg/kg
Chlorpyrifos	<0.2 mg/kg
Chlorpyrifos-methyl	<0.1 mg/kg
Chlorthal-dimethyl	<0.01 mg/kg
Cyfluthrin I-IV	<0.1 mg/kg

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ANALYTICAL REPORT

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Received On: 18Oct2021
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Eurofins Sample Code: 111-2021-10180038
Client Sample Code: RGE1210720
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt:acceptable, 22°C
Sample Reference:

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Cyhalothrin, lambda-	<1 mg/kg
Cypermethrin I-IV	<1 mg/kg
DDT (sum)	<1.0 mg/kg
Deltamethrin	<0.5 mg/kg
Diazinon	<0.5 mg/kg
Dichlofluanid	<0.1 mg/kg
Dichlorvos	<1 mg/kg
Dicofol, o,p' & p,p'-	<0.5 mg/kg
Dimethoate and omethoate (sum of)	<0.1 mg/kg
Endosulfan (sum)	<3.0 mg/kg
Endrin	<0.05 mg/kg
Ethion	<2 mg/kg
Etrimfos	<0.05 mg/kg
Fenchlorophos (sum)	<0.1 mg/kg
Fenitrothion	<0.5 mg/kg
Fenpropathrin	<0.03 mg/kg
Fensulfothion (sum)	<0.05 mg/kg
Fenthion (sum)	<0.05 mg/kg
Fenvalerate I&II	<1.5 mg/kg
Flucythrinate I&II	<0.05 mg/kg
Fluvalinate, tau- I&II	<0.05 mg/kg
Fonofos	<0.05 mg/kg
Heptachlor (sum)	<0.05 mg/kg
Hexachlorobenzene (HCB)	<0.1 mg/kg
Hexachlorocyclohexane isomers (other than gamma)	<0.3 mg/kg
Lindane (gamma-HCH)	<0.6 mg/kg
Malathion and malaoxon (sum of)	<1 mg/kg
Mecarbam	<0.05 mg/kg
Methacrifos	<0.05 mg/kg
Methamidophos	<0.05 mg/kg
Methidathion	<0.2 mg/kg
Methoxychlor	<0.05 mg/kg
Mirex	<0.01 mg/kg

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Client Sample Code: RGE1210720
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt:acceptable, 22°C
Sample Reference:

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Monocrotophos	<0.1 mg/kg
Parathion-ethyl and paraoxon-ethyl (sum of)	<0.5 mg/kg
Parathion-methyl and paraoxon-methyl (sum of)	<0.2 mg/kg
Pendimethalin	<0.1 mg/kg
Pentachloranisole	<0.01 mg/kg
Permethrin (sum of isomers)	<1 mg/kg
Phosalone	<0.1 mg/kg
Phosmet	<0.05 mg/kg
Piperonyl butoxide	<3 mg/kg
Pirimiphos-ethyl	<0.05 mg/kg
Pirimiphos-methyl (sum)	<4 mg/kg
Procymidone	<0.1 mg/kg
Profenofos	<0.1 mg/kg
Prothiofos	<0.05 mg/kg
Pyrethrum (total isomers)	<3 mg/kg
Quinalphos	<0.05 mg/kg
Quintozene (sum)	<1 mg/kg
S 421	<0.02 mg/kg
Tecnazene	<0.05 mg/kg
Tetradifon	<0.3 mg/kg
Vinclozolin	<0.4 mg/kg

QA0T0 - Standard Addition Confirmation <USP561>	Reference	Accreditation	Completed	Sub
	No Reference	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Standard Addition Confirmation	not required

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, LA

ANDERSON GLOBAL GROUP, LLC

KERRI-LYNN SWANSON
2030 Main Street
Suite 150
Irvine, CA 92614

ANALYTICAL REPORT

AR-21-QR-032038-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Respectfully Submitted,

Viridiana Castro
Assistant Laboratory Manager

Results shown in this report relate solely to the item submitted for analysis. | Any opinions/interpretations expressed on this report are given independent of the laboratory's scope of accreditation. | All results are reported on an "As Received" basis unless otherwise stated. | Reports shall not be reproduced except in full without written permission of Eurofins Scientific, Inc. | All work done in accordance with Eurofins General Terms and Conditions of Sale: www.eurofinsus.com/terms_and_conditions.pdf | √ indicates a subcontract test to a different lab. Lab(s) are listed at end of the report. For further details about the performing labs please contact your customer service contact at Eurofins. Measurement of uncertainty can be obtained upon request.

Eurofins Microbiology Laboratories (Los Angeles)

Eurofins Microbiology Laboratories (Los Angeles)

11390 Knott Ave
Garden Grove, CA 92841
+1 714 892 0208
Micro-LosAngeles@EurofinsUS.com

ANDERSON GLOBAL GROUP, LLC

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2030 Main Street
Suite 150
Irvine, CA 92614

ANALYTICAL REPORT

AR-21-QR-032039-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Eurofins Sample Code: 111-2021-10180039
Client Sample Code: RGE1210714
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt: acceptable, 22°C
Sample Reference:

QA0SW - Dithiocarbamates by LC-MS/MS per USP <561>	Reference	Accreditation	Completed	Sub
	Anal Bioanal Chem, 2008,392(5), 969-978.Modified.	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Dithiocarbamates (as CS2)	<2.00 mg/kg

QA0SY - Bromide, inorganic (GC-MS) <USP 561>	Reference	Accreditation	Completed	Sub
	EURL-SRM, Bromine Containing Fumigants	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Total Inorganic Bromide	<125 mg/kg

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Acephate	<0.1 mg/kg
Alachlor	<0.05 mg/kg
Aldrin and dieldrin (sum of)	<0.05 mg/kg
Azinphos-ethyl	<0.1 mg/kg
Azinphos-methyl	<1 mg/kg
Bromophos-ethyl	<0.05 mg/kg
Bromophos-methyl	<0.05 mg/kg
Bromopropylate	<3 mg/kg
Chlordane (sum)	<0.05 mg/kg
Chlorfenvinphos	<0.5 mg/kg
Chlorpyrifos	<0.2 mg/kg
Chlorpyrifos-methyl	<0.1 mg/kg
Chlorthal-dimethyl	<0.01 mg/kg
Cyfluthrin I-IV	<0.1 mg/kg

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Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Eurofins Sample Code: 111-2021-10180039
Client Sample Code: RGE1210714
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt:aceptable, 22°C
Sample Reference:

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Cyhalothrin, lambda-	<1 mg/kg
Cypermethrin I-IV	<1 mg/kg
DDT (sum)	<1.0 mg/kg
Deltamethrin	<0.5 mg/kg
Diazinon	<0.5 mg/kg
Dichlofluanid	<0.1 mg/kg
Dichlorvos	<1 mg/kg
Dicofol, o,p' & p,p'-	<0.5 mg/kg
Dimethoate and omethoate (sum of)	<0.1 mg/kg
Endosulfan (sum)	<3.0 mg/kg
Endrin	<0.05 mg/kg
Ethion	<2 mg/kg
Etrimfos	<0.05 mg/kg
Fenchlorophos (sum)	<0.1 mg/kg
Fenitrothion	<0.5 mg/kg
Fenpropathrin	<0.03 mg/kg
Fensulfothion (sum)	<0.05 mg/kg
Fenthion (sum)	<0.05 mg/kg
Fenvalerate I&II	<1.5 mg/kg
Flucythrinate I&II	<0.05 mg/kg
Fluvalinate, tau- I&II	<0.05 mg/kg
Fonofos	<0.05 mg/kg
Heptachlor (sum)	<0.05 mg/kg
Hexachlorobenzene (HCB)	<0.1 mg/kg
Hexachlorocyclohexane isomers (other than gamma)	<0.3 mg/kg
Lindane (gamma-HCH)	<0.6 mg/kg
Malathion and malaoxon (sum of)	<1 mg/kg
Mecarbam	<0.05 mg/kg
Methacrifos	<0.05 mg/kg
Methamidophos	<0.05 mg/kg
Methidathion	<0.2 mg/kg
Methoxychlor	<0.05 mg/kg
Mirex	<0.01 mg/kg

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ANALYTICAL REPORT

AR-21-QR-032039-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Eurofins Sample Code: 111-2021-10180039
Client Sample Code: RGE1210714
Sample Description: Tapioca Starch

Sample Registration Date: 18Oct2021
Condition Upon Receipt: acceptable, 22°C
Sample Reference:

QA0SZ - Pesticides <USP 561> (LC-MS/MS and GC-MS/MS)	Reference	Accreditation	Completed	Sub
	USP 561 (Modified)	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Monocrotophos	<0.1 mg/kg
Parathion-ethyl and paraoxon-ethyl (sum of)	<0.5 mg/kg
Parathion-methyl and paraoxon-methyl (sum of)	<0.2 mg/kg
Pendimethalin	<0.1 mg/kg
Pentachloranisole	<0.01 mg/kg
Permethrin (sum of isomers)	<1 mg/kg
Phosalone	<0.1 mg/kg
Phosmet	<0.05 mg/kg
Piperonyl butoxide	<3 mg/kg
Pirimiphos-ethyl	<0.05 mg/kg
Pirimiphos-methyl (sum)	<4 mg/kg
Procymidone	<0.1 mg/kg
Profenofos	<0.1 mg/kg
Prothiofos	<0.05 mg/kg
Pyrethrum (total isomers)	<3 mg/kg
Quinalphos	<0.05 mg/kg
Quintozene (sum)	<1 mg/kg
S 421	<0.02 mg/kg
Tecnazene	<0.05 mg/kg
Tetradifon	<0.3 mg/kg
Vinclozolin	<0.4 mg/kg

QA0T0 - Standard Addition Confirmation <USP561>	Reference	Accreditation	Completed	Sub
	No Reference	ISO/IEC 17025:2017 A2LA 2993.01	26Oct2021	1

Parameter	Result
Standard Addition Confirmation	not required

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, LA

ANDERSON GLOBAL GROUP, LLC

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2030 Main Street
Suite 150
Irvine, CA 92614

ANALYTICAL REPORT

AR-21-QR-032039-01

Client Code: QR0000052

Received On: 18Oct2021
Reported On: 26Oct2021

Respectfully Submitted,

Viridiana Castro
Assistant Laboratory Manager

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AGG's resistant dextrin

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order Number:	**2021-010754**	**Completed Date:**	29-Oct-2021
		Submitted Date:	19-Oct-2021
Submitter:	Kerri-Lynn Swanson		
Company:	Anderson Global Group		
Company Address:	2030 Main St Suite 430 Irvine, CA 92614		
Results Email:	kerrilynns@andersonglobalgroup.com		
Invoice Email:	kerrilynns@andersonglobalgroup.com		
Purchase Order:	CC		

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
Medallion Labs' services, including this report, are provided subject to all provisions of Medallion's Standard Terms and Conditions, a copy of which appears at www.medallionlabs.com. Unless otherwise noted above, samples were received in acceptable condition and analyzed as received.

AGG's resistant dextrin

Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2021-010754-01	**Company:**	Anderson Global Group
Customer Sample ID:	Tapioca Starch 1		
Sample Description:	Lot# RGE1210720		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	29-Oct-2021
	Aflatoxin B2	<1.2 ppb	29-Oct-2021
	Aflatoxin G1	<1.1 ppb	29-Oct-2021
	Aflatoxin G2	<1.6 ppb	29-Oct-2021
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	29-Oct-2021
	Fumonisin B2	<0.1 ppm	29-Oct-2021
	Fumonisin B3	<0.1 ppm	29-Oct-2021
[1] [2] Mercury	Mercury	<0.010 mg/kg	26-Oct-2021
Metals (ICP-MS)	Arsenic	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Cadmium	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Lead	<10 ppb	25-Oct-2021
[1] [2] Ochratoxin LCMS	Ochratoxin A	<1.1 ppb	29-Oct-2021
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.1 ppm	29-Oct-2021
	Acetyldeoxynivalenol	<0.1 ppm	29-Oct-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	3.1E4 CFU / g	21-Oct-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	21-Oct-2021
Mold using DRBC	Mold	300 CFU / g	25-Oct-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	20-Oct-2021
Staphylococcus aureus using Petrifilm	Staphylococcus aureus	<10 CFU / g	20-Oct-2021
Yeast using DRBC	Yeast	<10 CFU / g	25-Oct-2021

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[1] This analysis is performed by a partner lab.
[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

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Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2021-010754-02	**Company:**	Anderson Global Group
Customer Sample ID:	Tapioca Starch 2		
Sample Description:	Lot# RGE1210717		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	29-Oct-2021
	Aflatoxin B2	<1.2 ppb	29-Oct-2021
	Aflatoxin G1	<1.1 ppb	29-Oct-2021
	Aflatoxin G2	<1.6 ppb	29-Oct-2021
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	29-Oct-2021
	Fumonisin B2	<0.1 ppm	29-Oct-2021
	Fumonisin B3	<0.1 ppm	29-Oct-2021
[1] [2] Mercury	Mercury	<0.010 mg/kg	26-Oct-2021
Metals (ICP-MS)	Arsenic	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Cadmium	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Lead	<10 ppb	25-Oct-2021
[1] [2] Ochratoxin LCMS	Ochratoxin A	<1.1 ppb	29-Oct-2021
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.1 ppm	29-Oct-2021
	Acetyldeoxynivalenol	<0.1 ppm	29-Oct-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	2.3E4 est. CFU / g	21-Oct-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	21-Oct-2021
Mold using DRBC	Mold	200 CFU / g	25-Oct-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	20-Oct-2021
Staphylococcus aureus using Petrifilm	Staphylococcus aureus	<10 CFU / g	20-Oct-2021
Yeast using DRBC	Yeast	<10 CFU / g	25-Oct-2021

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
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Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2021-010754-03	**Company:**	Anderson Global Group
Customer Sample ID:	Tapioca Starch 3		
Sample Description:	Lot# RGE1210714		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	29-Oct-2021
	Aflatoxin B2	<1.2 ppb	29-Oct-2021
	Aflatoxin G1	<1.1 ppb	29-Oct-2021
	Aflatoxin G2	<1.6 ppb	29-Oct-2021
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	29-Oct-2021
	Fumonisin B2	<0.1 ppm	29-Oct-2021
	Fumonisin B3	<0.1 ppm	29-Oct-2021
[1] [2] Mercury	Mercury	<0.010 mg/kg	26-Oct-2021
Metals (ICP-MS)	Arsenic	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Cadmium	<10 ppb	25-Oct-2021
Metals (ICP-MS)	Lead	<10 ppb	25-Oct-2021
[1] [2] Ochratoxin LCMS	Ochratoxin A	<1.1 ppb	29-Oct-2021
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.1 ppm	29-Oct-2021
	Acetyldeoxynivalenol	<0.1 ppm	29-Oct-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	3.0E4 CFU / g	21-Oct-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	21-Oct-2021
Mold using DRBC	Mold	170 CFU / g	25-Oct-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	20-Oct-2021
Staphylococcus aureus using Petrifilm	Staphylococcus aureus	<10 CFU / g	20-Oct-2021
Yeast using DRBC	Yeast	<10 CFU / g	25-Oct-2021

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www.medallionlabs.com 800-245-5615 info@medlabs.com

Results Approved By: Elliot McSherry
(Authorized Reviewer)

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[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

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www.medallionlabs.com 800-245-5615 info@medlabs.com

Analytical Method References:

Method Name	Method Reference
Aflatoxin LCMS	Please contact for Method Details
Fumonisin LCMS	Please contact for Method Details
Mercury	Please contact for Method Details
Metals (ICP-MS)	AOAC: 993.14*, AOAC: 2015.06*
Ochratoxin LCMS	Please contact for Method Details
Vomitoxin LCMS	Please contact for Method Details

Micro Method References:

Method Name	Method Reference
Aerobic Plate Count using PCA	FDA BAM CH 3*
E. coli using Petrifilm	AOAC 991.14
Mold using DRBC	FDA BAM CH 18*, Compendium*
Salmonella by ELFA	AOAC 2013.01*
Staphylococcus aureus using Petrifilm	AOAC 2003.07
Yeast using DRBC	FDA BAM CH 18*, Compendium*

* This method has been modified.

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[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Annex D. Cyanogenic Glycosides of FiberSMART®-tapioca

Received Date: 10/15/2021
Report Date: 10/22/2021

ABC TESTING, INC

Advanced Botanical Consulting & Testing Inc.

1169 Warner Ave, Tustin, CA 92780, Phone:(714)259-0384 Fax: (714)259-0385

Anderson Global Group
2030 Main Street, Suite 430
Irvine, CA 92614

ATTN: Kerri-Lynn Swanson
TEL# (949) 502-4770
FAX# (949) 502-4775

Sample Name: FiberSMART Tapioca 1
Item#
Lab# 364931

Lot# 20200907017
PO#

Analysis:	Method:	Result:	Spec:
Cyanogenic Glycosides	AOAC 936.11	N.D. < 5 ppm	N.D. (<5 ppm)

AOAC casp Cannabis Analytical Science Program

Approved by: [redacted]
Wendi Wang, PhD, President

ABC Testing is an ISO accredited laboratory that specializes in the testing of botanical ingredients, dietary supplements, and foods. ABC is not an FDA drug registered facility, therefore any data or results provided by ABC are not intended to fulfill any requirements under the drug cGMPs dictated in 21 CFR Parts 210 and 211.

Received Date: 10/15/2021
Report Date: 10/22/2021

ABC TESTING, INC

Advanced Botanical Consulting & Testing Inc.

1169 Warner Ave, Tustin, CA 92780, Phone:(714)259-0384 Fax: (714)259-0385

Anderson Global Group
2030 Main Street, Suite 430
Irvine, CA 92614

ATTN: Kerri-Lynn Swanson
TEL# (949) 502-4770
FAX# (949) 502-4775

Sample Name: FiberSMART Tapioca 2
Item#
Lab# 364932
Lot# 20200622037
PO#

Analysis:	Method:	Result:	Spec:
Cyanogenic Glycosides	AOAC 936.11	N.D. < 5 ppm	N.D. (<5 ppm)

AOAC casp Cannabis Analytical Science Program

Approved by: [redacted]
Wendi Wang, PhD, President

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Received Date: 10/15/2021
Report Date: 10/22/2021

ABC TESTING, INC

Advanced Botanical Consulting & Testing Inc.

1169 Warner Ave, Tustin, CA 92780, Phone:(714)259-0384 Fax: (714)259-0385

Anderson Global Group
2030 Main Street, Suite 430
Irvine, CA 92614

ATTN: Kerri-Lynn Swanson
TEL# (949) 502-4770
FAX# (949) 502-4775

Sample Name: FiberSMART Tapioca 3
Item#
Lab# 364933
Lot# 20200402037
PO#

Analysis:	Method:	Result:	Spec:
Cyanogenic Glycosides	AOAC 936.11	N.D. < 5 ppm	N.D. (<5 ppm)

AOAC casp Cannabis Analytical Science Program

Approved by: [redacted]
Wendi Wang, PhD, President

ABC Testing is an ISO accredited laboratory that specializes in the testing of botanical ingredients, dietary supplements, and foods. ABC is not an FDA drug registered facility, therefore any data or results provided by ABC are not intended to fulfill any requirements under the drug cGMPs dictated in 21 CFR Parts 210 and 211.

Annex E. Certificates of Analysis for Finished Ingredient

Final Report

Order Number:	**2021-008506**	**Completed Date:**	23-Sep-2021
		Submitted Date:	16-Aug-2021
Submitter:	Kerri-Lynn Swanson		
Company:	Anderson Global Group		
Company Address:	2030 Main St		
	Suite 430		
	Irvine, CA 92614		
Results Email:	kerrilynns@andersonglobalgroup.com		
Invoice Email:	kerrilynns@andersonglobalgroup.com		
Purchase Order:	CC		

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Medallion Labs

www.medallionlabs.com 800-245-5615 info@medlabs.com

Final Report

Order # Sample ID:	2021-008506-01	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Powder		
Sample Description:	Lot# 20200622037		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	07-Sep-2021
² Calories	Calories	380 Calories/100 g	17-Sep-2021
	Calories, 2020	277 Calories/100 g	17-Sep-2021
	Calories from Fat	0 Calories/100 g	17-Sep-2021
	Calories from Saturated Fat	0 Calories/100 g	17-Sep-2021
	Calories (Insoluble Fiber Subtracted)	376 Calories/100 g	17-Sep-2021
² Carbohydrates	Carbohydrates	94.9 %	17-Sep-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	17-Sep-2021
	Saturated Fat	<LOQ %	17-Sep-2021
	Monounsaturated Fat	<LOQ %	17-Sep-2021
	cis-cis Polyunsaturated Fat	<LOQ %	17-Sep-2021
	trans Fat	<LOQ %	17-Sep-2021
² Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	47.3 %	14-Sep-2021
	Dietary Fiber HPLC	39.7 %	14-Sep-2021
	Total Dietary Fiber	87.0 %	14-Sep-2021
Fiber (AOAC 991.43)	Insoluble Dietary Fiber	0.9 %	24-Aug-2021
	Soluble Dietary Fiber	49.3 %	24-Aug-2021
	Total Dietary Fiber	50.2 %	24-Aug-2021
Metals (DMA)	Mercury	<4.00 ppb	19-Aug-2021
Metals (ICP-MS)	Arsenic	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Cadmium	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Lead	<10 ppb	24-Aug-2021

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Final Report

Order # Sample ID:	2021-008506-01	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Powder		
Sample Description:	Lot# 20200622037		

Analytical Testing

Method:	Component:	Result:	Test Date:
Moisture by Vacuum Oven	Moisture	5.125 %	19-Aug-2021
Protein	Protein Factor	6.25	10-Sep-2021
	Protein	<0.781 %	10-Sep-2021
Sugars	Galactose	<0.1 %	20-Aug-2021
	Fructose	<0.1 %	20-Aug-2021
	Glucose	0.577 %	20-Aug-2021
	Sucrose	<0.1 %	20-Aug-2021
	Maltose	<0.1 %	20-Aug-2021
	Lactose	<0.1 %	20-Aug-2021
	Total Sugar	0.577 %	20-Aug-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	19-Aug-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Aug-2021
Mold using DRBC	Mold	<10 CFU / g	23-Aug-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	18-Aug-2021
Yeast using DRBC	Yeast	<10 CFU / g	23-Aug-2021

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AGG's resistant dextrin

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Final Report

Order # Sample ID:	2021-008506-02	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Powder 2		
Sample Description:	Lot# 2020090717		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	0.028 %	19-Aug-2021
[2] Calories	Calories	384 Calories/100 g	30-Aug-2021
	Calories, 2020	279 Calories/100 g	30-Aug-2021
	Calories from Fat	0 Calories/100 g	30-Aug-2021
	Calories from Saturated Fat	0 Calories/100 g	30-Aug-2021
	Calories (Insoluble Fiber Subtracted)	382 Calories/100 g	30-Aug-2021
[2] Carbohydrates	Carbohydrates	96.0 %	30-Aug-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	30-Aug-2021
	Saturated Fat	<LOQ %	30-Aug-2021
	Monounsaturated Fat	<LOQ %	30-Aug-2021
	cis-cis Polyunsaturated Fat	<LOQ %	30-Aug-2021
	trans Fat	<LOQ %	30-Aug-2021
[2] Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	44.8 %	25-Aug-2021
	Dietary Fiber HPLC	40.4 %	25-Aug-2021
	Total Dietary Fiber	85.2 %	25-Aug-2021
Fiber (AOAC 991.43)	Insoluble Dietary Fiber	0.5 %	24-Aug-2021
	Soluble Dietary Fiber	51.2 %	24-Aug-2021
	Total Dietary Fiber	51.7 %	24-Aug-2021
Metals (DMA)	Mercury	<4.00 ppb	19-Aug-2021
Metals (ICP-MS)	Arsenic	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Cadmium	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Lead	<10 ppb	24-Aug-2021

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Final Report

Order # Sample ID:	2021-008506-02	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Powder 2		
Sample Description:	Lot# 2020090717		

Analytical Testing

Method:	Component:	Result:	Test Date:
Moisture by Vacuum Oven	Moisture	4.008 %	19-Aug-2021
Protein	Protein Factor	6.25	26-Aug-2021
	Protein	<0.781 %	26-Aug-2021
Sugars	Galactose	<0.1 %	20-Aug-2021
	Fructose	0.120 %	20-Aug-2021
	Glucose	0.485 %	20-Aug-2021
	Sucrose	0.125 %	20-Aug-2021
	Maltose	<0.1 %	20-Aug-2021
	Lactose	<0.1 %	20-Aug-2021
	Total Sugar	0.731 %	20-Aug-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	10 est. CFU / g	19-Aug-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Aug-2021
Mold using DRBC	Mold	<10 CFU / g	23-Aug-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	18-Aug-2021
Yeast using DRBC	Yeast	<10 CFU / g	23-Aug-2021

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Final Report

Order # Sample ID:	2021-008506-03	Company:	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Powder 3		
Sample Description:	Lot# 20191007034		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	0.036 %	19-Aug-2021
[2] Calories	Calories	376 Calories/100 g	30-Aug-2021
	Calories, 2020	269 Calories/100 g	30-Aug-2021
	Calories from Fat	0 Calories/100 g	30-Aug-2021
	Calories from Saturated Fat	0 Calories/100 g	30-Aug-2021
	Calories (Insoluble Fiber Subtracted)	373 Calories/100 g	30-Aug-2021
[2] Carbohydrates	Carbohydrates	94.1 %	30-Aug-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	30-Aug-2021
	Saturated Fat	<LOQ %	30-Aug-2021
	Monounsaturated Fat	<LOQ %	30-Aug-2021
	cis-cis Polyunsaturated Fat	<LOQ %	30-Aug-2021
	trans Fat	<LOQ %	30-Aug-2021
[2] Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	46.3 %	25-Aug-2021
	Dietary Fiber HPLC	39.3 %	25-Aug-2021
	Total Dietary Fiber	85.6 %	25-Aug-2021
Fiber (AOAC 991.43)	Insoluble Dietary Fiber	0.8 %	24-Aug-2021
	Soluble Dietary Fiber	52.0 %	24-Aug-2021
	Total Dietary Fiber	52.8 %	24-Aug-2021
Metals (DMA)	Mercury	<4.00 ppb	19-Aug-2021
Metals (ICP-MS)	Arsenic	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Cadmium	<10 ppb	24-Aug-2021
Metals (ICP-MS)	Lead	<10 ppb	24-Aug-2021

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Final Report

Order # Sample ID: 2021-008506-03 **Company:** Anderson Global Group
Customer Sample ID: FiberSMART Tapioca Powder 3
Sample Description: Lot# 20191007034

Analytical Testing

Method:	Component:	Result:	Test Date:
Moisture by Vacuum Oven	Moisture	5.903 %	19-Aug-2021
Protein	Protein Factor	6.25	26-Aug-2021
	Protein	<0.781 %	26-Aug-2021
Sugars	Galactose	<0.1 %	20-Aug-2021
	Fructose	<0.1 %	20-Aug-2021
	Glucose	0.816 %	20-Aug-2021
	Sucrose	<0.1 %	20-Aug-2021
	Maltose	<0.1 %	20-Aug-2021
	Lactose	<0.1 %	20-Aug-2021
	Total Sugar	0.816 %	20-Aug-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	19-Aug-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Aug-2021
Mold using DRBC	Mold	<10 CFU / g	23-Aug-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	18-Aug-2021
Yeast using DRBC	Yeast	<10 CFU / g	23-Aug-2021

Results Approved By: Jill Zigan
(Authorized Reviewer)

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Final Report

Analytical Method References:

Method Name	Method Reference
Ash	AOAC: 923.03*
Calories	Internal Calculation
Carbohydrates	Internal Calculation
Fat (Gas Chromatography)	AOAC: 996.06*
Fiber (AOAC 2009.01)	AOAC 2009.01*
Fiber (AOAC 991.43)	AOAC: 991.43*
Metals (DMA)	EPA 7473
Metals (ICP-MS)	AOAC: 993.14*, AOAC: 2015.06*
Moisture by Vacuum Oven	AOAC: 945.43*, 934.01*
Protein	AACC 46-30*; AOAC 992.15*
Sugars	AOAC: 977.20*

Micro Method References:

Method Name	Method Reference
Aerobic Plate Count using PCA	FDA BAM CH 3*
E. coli using Petrifilm	AOAC 991.14
Mold using DRBC	FDA BAM CH 18*, Compendium*
Salmonella by ELFA	AOAC 2013.01*
Yeast using DRBC	FDA BAM CH 18*, Compendium*

* This method has been modified.

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Revised Final Report

Order Number:	**2021-009653**	**Completed Date:**	14-Oct-2021
		Submitted Date:	20-Sep-2021
Submitter:	Kerri-Lynn Swanson		
Company:	Anderson Global Group		
Company Address:	2030 Main St Suite 430 Irvine, CA 92614		
Results Email:	kerrilynns@andersonglobalgroup.com		
Invoice Email:	kerrilynns@andersonglobalgroup.com		
Purchase Order:	CC		

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Revised Final Report

Order # Sample ID:	2021-009653-01	Company:	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 1		
Sample Description:	Lot# 20191106013		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	24-Sep-2021
[2] Calories	Calories	289 Calories/100 g	29-Sep-2021
	Calories, 2020	289 Calories/100 g	29-Sep-2021
	Calories from Fat	0 Calories/100 g	29-Sep-2021
	Calories from Saturated Fat	0 Calories/100 g	29-Sep-2021
[2] Carbohydrates	Carbohydrates	72.2 %	29-Sep-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	29-Sep-2021
	Saturated Fat	<LOQ %	29-Sep-2021
	Monounsaturated Fat	<LOQ %	29-Sep-2021
	cis-cis Polyunsaturated Fat	<LOQ %	29-Sep-2021
	trans Fat	<LOQ %	29-Sep-2021
[3] Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	33.9 %	14-Oct-2021
	Dietary Fiber HPLC	31.7 %	14-Oct-2021
	Total Dietary Fiber	65.6 %	14-Oct-2021
Metals (DMA)	Mercury	<4.00 ppb	23-Sep-2021
Metals (ICP-MS)	Arsenic	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Cadmium	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Lead	<10 ppb	28-Sep-2021
Moisture by Vacuum Oven	Moisture	27.751 %	23-Sep-2021
Protein	Protein Factor	6.25	28-Sep-2021
	Protein	<0.781 %	28-Sep-2021
Sugars	Galactose	<0.1 %	23-Sep-2021
	Fructose	<0.1 %	23-Sep-2021

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[3] Reported value has been revised from original report # 48153

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Revised Final Report

Order # Sample ID:	2021-009653-01	Company:	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 1		
Sample Description:	Lot# 20191106013		

Analytical Testing

Method:	Component:	Result:	Test Date:
Sugars	Glucose	0.640 %	23-Sep-2021
	Sucrose	<0.1 %	23-Sep-2021
	Maltose	<0.1 %	23-Sep-2021
	Lactose	<0.1 %	23-Sep-2021
	Total Sugar	0.640 %	23-Sep-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	23-Sep-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Sep-2021
Mold using DRBC	Mold	<10 CFU / g	27-Sep-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	23-Sep-2021
Yeast using DRBC	Yeast	<10 CFU / g	27-Sep-2021

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Revised Final Report

Order # Sample ID:	2021-009653-02	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 2		
Sample Description:	Lot# 20200303033		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	24-Sep-2021
[2] Calories	Calories	289 Calories/100 g	29-Sep-2021
	Calories, 2020	289 Calories/100 g	29-Sep-2021
	Calories from Fat	0 Calories/100 g	29-Sep-2021
	Calories from Saturated Fat	0 Calories/100 g	29-Sep-2021
[2] Carbohydrates	Carbohydrates	72.1 %	29-Sep-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	29-Sep-2021
	Saturated Fat	<LOQ %	29-Sep-2021
	Monounsaturated Fat	<LOQ %	29-Sep-2021
	cis-cis Polyunsaturated Fat	<LOQ %	29-Sep-2021
	trans Fat	<LOQ %	29-Sep-2021
[3] Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	30.9 %	14-Oct-2021
	Dietary Fiber HPLC	34.5 %	14-Oct-2021
	Total Dietary Fiber	65.4 %	14-Oct-2021
Metals (DMA)	Mercury	<4.00 ppb	23-Sep-2021
Metals (ICP-MS)	Arsenic	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Cadmium	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Lead	<10 ppb	28-Sep-2021
Moisture by Vacuum Oven	Moisture	27.854 %	23-Sep-2021
Protein	Protein Factor	6.25	28-Sep-2021
	Protein	<0.781 %	28-Sep-2021
Sugars	Galactose	<0.1 %	23-Sep-2021
	Fructose	<0.1 %	23-Sep-2021

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Revised Final Report

Order # Sample ID:	2021-009653-02	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 2		
Sample Description:	Lot# 20200303033		

Analytical Testing

Method:	Component:	Result:	Test Date:
Sugars	Glucose	0.973 %	23-Sep-2021
	Sucrose	<0.1 %	23-Sep-2021
	Maltose	<0.1 %	23-Sep-2021
	Lactose	<0.1 %	23-Sep-2021
	Total Sugar	0.973 %	23-Sep-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	23-Sep-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Sep-2021
Mold using DRBC	Mold	<10 CFU / g	27-Sep-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	23-Sep-2021
Yeast using DRBC	Yeast	<10 CFU / g	27-Sep-2021

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Revised Final Report

Order # Sample ID:	2021-009653-03	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 3		
Sample Description:	Lot# 20210311023		

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	24-Sep-2021
[2] Calories	Calories	287 Calories/100 g	29-Sep-2021
	Calories, 2020	287 Calories/100 g	29-Sep-2021
	Calories from Fat	0 Calories/100 g	29-Sep-2021
	Calories from Saturated Fat	0 Calories/100 g	29-Sep-2021
[2] Carbohydrates	Carbohydrates	71.7 %	29-Sep-2021
Fat (Gas Chromatography)	Total Fat	<LOQ %	29-Sep-2021
	Saturated Fat	<LOQ %	29-Sep-2021
	Monounsaturated Fat	<LOQ %	29-Sep-2021
	cis-cis Polyunsaturated Fat	<LOQ %	29-Sep-2021
	trans Fat	<LOQ %	29-Sep-2021
[3] Fiber (AOAC 2009.01)	Dietary Fiber Gravimetric	29.8 %	14-Oct-2021
	Dietary Fiber HPLC	35.8 %	14-Oct-2021
	Total Dietary Fiber	65.6 %	14-Oct-2021
Metals (DMA)	Mercury	<4.00 ppb	23-Sep-2021
Metals (ICP-MS)	Arsenic	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Cadmium	<10 ppb	28-Sep-2021
Metals (ICP-MS)	Lead	<10 ppb	28-Sep-2021
Moisture by Vacuum Oven	Moisture	28.337 %	23-Sep-2021
Protein	Protein Factor	6.25	28-Sep-2021
	Protein	<0.781 %	28-Sep-2021
Sugars	Galactose	<0.1 %	23-Sep-2021
	Fructose	<0.1 %	23-Sep-2021

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Revised Final Report

Order # Sample ID:	2021-009653-03	**Company:**	Anderson Global Group
Customer Sample ID:	FiberSMART Tapioca Syrup 3		
Sample Description:	Lot# 20210311023		

Analytical Testing

Method:	Component:	Result:	Test Date:
Sugars	Glucose	0.878 %	23-Sep-2021
	Sucrose	<0.1 %	23-Sep-2021
	Maltose	<0.1 %	23-Sep-2021
	Lactose	<0.1 %	23-Sep-2021
	Total Sugar	0.878 %	23-Sep-2021

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	23-Sep-2021
E. coli using Petrifilm	E. coli	<10 CFU / g	23-Sep-2021
Mold using DRBC	Mold	<10 CFU / g	27-Sep-2021
Salmonella by ELFA	Salmonella	Negative / 25 grams	23-Sep-2021
Yeast using DRBC	Yeast	<10 CFU / g	27-Sep-2021

Results Approved By: Jamie Reese
(Authorized Reviewer)

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Analytical Method References:

Method Name	Method Reference
Ash	AOAC: 923.03*
Calories	Internal Calculation
Carbohydrates	Internal Calculation
Fat (Gas Chromatography)	AOAC: 996.06*
Fiber (AOAC 2009.01)	AOAC 2009.01*
Metals (DMA)	EPA 7473
Metals (ICP-MS)	AOAC: 993.14*, AOAC: 2015.06*
Moisture by Vacuum Oven	AOAC: 934.06, 969.38, 977.21*
Protein	AACC 46-30*; AOAC 992.15*
Sugars	AOAC: 977.20*

Micro Method References:

Method Name	Method Reference
Aerobic Plate Count using PCA	FDA BAM CH 3*
E. coli using Petrifilm	AOAC 991.14
Mold using DRBC	FDA BAM CH 18*, Compendium*
Salmonella by ELFA	AOAC 2013.01*
Yeast using DRBC	FDA BAM CH 18*, Compendium*

* This method has been modified.

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
Medallion Labs' services, including this report, are provided subject to all provisions of Medallion's Standard Terms and Conditions, a copy of which appears at www.medallionlabs.com. Unless otherwise noted above, samples were received in acceptable condition and analyzed as received.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

[3] Reported value has been revised from original report # 48153

Annex F. NHANES Food Codes Included in EDI Calculations

11111170	Milk, calcium fortified, fat free (skim)
11112110	Milk, reduced fat (2%)
11112120	Milk, acidophilus, low fat (1%)
11112210	Milk, low fat (1%)
11113000	Milk, fat free (skim)
11114300	Milk, lactose free, low fat (1%)
11114320	Milk, lactose free, fat free (skim)
11114330	Milk, lactose free, reduced fat (2%)
11411200	Yogurt, low fat milk, plain
11411410	Yogurt, Greek, low fat milk, plain
11432000	Yogurt, low fat milk, fruit
11433000	Yogurt, nonfat milk, fruit
11434010	Yogurt, Greek, low fat milk, fruit
11434020	Yogurt, Greek, nonfat milk, fruit
11434200	Yogurt, low fat milk, flavors other than fruit
11434300	Yogurt, nonfat milk, flavors other than fruit
11435020	Yogurt, Greek, low fat milk, flavors other than fruit
11435030	Yogurt, Greek, nonfat milk, flavors other than fruit
11446000	Yogurt parfait, low fat, with fruit
11460100	Frozen yogurt, chocolate
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
11511200	Chocolate milk, ready to drink, reduced fat
11511300	Chocolate milk, ready to drink, fat free
11511400	Chocolate milk, ready to drink, low fat
11511550	Chocolate milk, ready to drink, reduced sugar, NS as to milk
11511600	Chocolate milk, ready to drink, low fat (Nesquik)
11511610	Chocolate milk, ready to drink, fat free (Nesquik)
11511700	Chocolate milk, ready to drink, low fat, no sugar added (Nesquik)
11512020	Hot chocolate / Cocoa, ready to drink, made with nonfat milk
11513150	Chocolate milk, made from dry mix with reduced fat milk
11513200	Chocolate milk, made from dry mix with low fat milk
11513300	Chocolate milk, made from dry mix with fat free milk
11513360	Chocolate milk, made from reduced sugar mix with reduced fat milk
11513365	Chocolate milk, made from reduced sugar mix with low fat milk
11513382	Chocolate milk, made from dry mix with reduced fat milk (Nesquik)
11513383	Chocolate milk, made from dry mix with low fat milk (Nesquik)

11513384	Chocolate milk, made from dry mix with fat free milk (Nesquik)
11513392	Chocolate milk, made from no sugar added dry mix with reduced fat milk (Nesquik)
11513393	Chocolate milk, made from no sugar added dry mix with low fat milk (Nesquik)
11513550	Chocolate milk, made from syrup with reduced fat milk
11513600	Chocolate milk, made from syrup with low fat milk
11513700	Chocolate milk, made from syrup with fat free milk
11513802	Chocolate milk, made from light syrup with reduced fat milk
11513803	Chocolate milk, made from light syrup with low fat milk
11513804	Chocolate milk, made from light syrup with fat free milk
11514120	Hot chocolate / Cocoa, made with dry mix and reduced fat milk
11514130	Hot chocolate / Cocoa, made with dry mix and low fat milk
11514140	Hot chocolate / Cocoa, made with dry mix and fat free milk
11514310	Hot chocolate / Cocoa, made with no sugar added dry mix and water
11514330	Hot chocolate / Cocoa, made with no sugar added dry mix and reduced fat milk
11514340	Hot chocolate / Cocoa, made with no sugar added dry mix and low fat milk
11514350	Hot chocolate / Cocoa, made with no sugar added dry mix and fat free milk
11519105	Strawberry milk, reduced fat
11519200	Strawberry milk, low fat
11519205	Strawberry milk, fat free
11519210	Strawberry milk, reduced sugar
11541130	Milk shake, home recipe, chocolate, light
11541135	Milk shake, home recipe, flavors other than chocolate, light
11830100	Hot chocolate / Cocoa, dry mix, not reconstituted
11830115	Hot chocolate / Cocoa, dry mix, no sugar added, not reconstituted
11830165	Chocolate beverage powder, light, dry mix, not reconstituted
12110100	Cream, light
12120110	Cream, half and half, fat free
12310300	Sour cream, reduced fat
12310350	Sour cream, light
12310370	Sour cream, fat free
13130300	Light ice cream, vanilla
13130310	Light ice cream, chocolate
13130320	Light ice cream, no sugar added, NS as to flavor
13130330	Light ice cream, no sugar added, flavors other than chocolate
13130340	Light ice cream, no sugar added, chocolate
13130600	Light ice cream, soft serve, flavors other than chocolate
13130620	Light ice cream, soft serve cone, flavors other than chocolate
13130630	Light ice cream, soft serve cone, chocolate
13130700	Soft serve, blended with candy or cookies, from fast food
13135000	Light ice cream sandwich, vanilla
13135010	Light ice cream sandwich, chocolate
13136000	Ice cream sandwich, made with light, no sugar added ice cream
13140000	Light ice cream bar, vanilla
13140100	Light ice cream bar, vanilla, chocolate coated

13140115	Light ice cream bar, chocolate
13140500	Light ice cream, cone, flavors other than chocolate
13140575	Light ice cream, no sugar added, cone, flavors other than chocolate
13140580	Light ice cream, no sugar added, cone, chocolate
13140660	Light ice cream, sundae, soft serve, chocolate or fudge topping, without whipped cream
13142100	Light ice cream cone, vanilla, prepackaged
13142110	Light ice cream cone, chocolate, prepackaged
13150000	Sherbet, all flavors
13160160	Fat free ice cream, no sugar added, flavors other than chocolate
13160400	Fat free ice cream, flavors other than chocolate
13160410	Fat free ice cream, chocolate
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk
13161600	Fudgesicle, light
13161630	Light ice cream, bar or stick, with low-calorie sweetener, chocolate coated
13200110	Pudding, chocolate, NFS
13210250	Pudding, chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13210290	Pudding, flavors other than chocolate, low calorie, containing artificial sweetener, NS as to from dry mix or ready-to-eat
13220210	Pudding, flavors other than chocolate, made from dry mix, sugar free
13220220	Pudding, chocolate, made from dry mix, sugar free
13220235	Pudding, ready-to-eat, chocolate, fat free
13230110	Pudding, flavors other than chocolate, ready-to-eat
13230120	Pudding, flavors other than chocolate, ready-to-eat, sugar free
13230130	Pudding, chocolate, ready-to-eat
13230140	Pudding, chocolate, ready-to-eat, sugar free
14010000	Cheese, NFS
14104110	Cheese, Cheddar, reduced fat
14104115	Cheese, Cheddar, nonfat or fat free
14106500	Cheese, Monterey, reduced fat
14107010	Cheese, Mozzarella, NFS
14107030	Cheese, Mozzarella, part skim
14107040	Cheese, Mozzarella, reduced sodium
14107060	Cheese, Mozzarella, nonfat or fat free
14107250	Cheese, Muenster, reduced fat
14108015	Cheese, Parmesan, dry grated, reduced fat
14108420	Cheese, provolone, reduced fat
14109020	Cheese, Swiss, reduced sodium
14109030	Cheese, Swiss, reduced fat
14110010	Cheese, Cheddar, reduced sodium
14120020	Cheese, Mexican blend, reduced fat
14204010	Cheese, cottage, low fat
14204020	Cheese, cottage, lowfat, with fruit
14206010	Cheese, cottage, lowfat, low sodium

14207010	Cheese, cottage, lowfat, lactose reduced
14303010	Cream cheese, light
14410120	Cheese, American, reduced fat
14410130	Cheese, American, nonfat or fat free
14410210	Cheese, American, reduced sodium
14410330	Cheese spread, American or Cheddar cheese base, reduced fat
14410380	Cream cheese spread, fat free
14420210	Cheese spread, cream cheese, light
27111000	Beef with tomato-based sauce
27111300	Beef stew, no potatoes, tomato-based sauce, Mexican style
27111310	Beef stew, no potatoes, tomato-based sauce, with chili peppers, Mexican style
27120100	Ham or pork with tomato-based sauce
27120110	Sausage with tomato-based sauce
27120130	Pork stew, no potatoes, tomato-based sauce, Mexican style
27120250	Frankfurters or hot dogs with tomato-based sauce
27135110	Veal parmigiana
27136050	Venison or deer with tomato-based sauce
27141000	Chicken or turkey cacciatore
27141030	Spaghetti sauce with poultry
27141035	Spaghetti sauce with poultry and added vegetables
27141050	Stewed chicken with tomato-based sauce, Mexican style
27146300	Chicken or turkey parmigiana
27150110	Shrimp cocktail
27150151	Spaghetti sauce with seafood
27150155	Spaghetti sauce with seafood and added vegetables
27150310	Fish with tomato-based sauce
27150330	Mussels with tomato-based sauce
27162010	Meat with tomato-based sauce
27162040	Spaghetti sauce with meat
27211100	Beef stew with potatoes, tomato-based sauce
27211110	Beef stew with potatoes, tomato-based sauce, Mexican style
27212100	Beef and noodles with tomato-based sauce
27213100	Beef and rice with tomato-based sauce
27213120	Porcupine balls with tomato-based sauce
27214110	Meat loaf made with beef, with tomato-based sauce
27220110	Pork and rice with tomato-based sauce
27220120	Sausage and rice with tomato-based sauce
27221150	Pork stew, with potatoes, tomato-based sauce, Mexican style
27242400	Chicken or turkey and noodles with tomato-based sauce
27243500	Chicken or turkey and rice with tomato-based sauce
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce
27250132	Shrimp and noodles with tomato sauce
27250810	Fish and rice with tomato-based sauce
27260100	Meat loaf made with beef and pork, with tomato-based sauce

27311310	Beef stew with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27311320	Beef stew with potatoes and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27311625	Beef, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27311630	Beef, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27313210	Beef, noodles, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27313220	Beef, noodles, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27315210	Beef, rice, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27315220	Beef, rice, and vegetables excluding carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27320080	Sausage, noodles, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27320100	Pork, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27320110	Pork, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27320350	Pork, rice, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27330210	Lamb or mutton stew with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27330220	Lamb or mutton stew with potatoes and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27336100	Venison or deer stew with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27336150	Venison or deer stew with potatoes and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27341055	Chicken or turkey, potatoes, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27341060	Chicken or turkey, potatoes, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27341510	Chicken or turkey stew with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27341520	Chicken or turkey stew with potatoes and vegetables excluding carrots, broccoli, and dark-green leafy; tomato- based sauce
27343520	Chicken or turkey, noodles, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce
27345510	Chicken or turkey, rice, and vegetables including carrots, broccoli, and/or dark-green leafy; tomato-based sauce
27345520	Chicken or turkey, rice, and vegetables excluding carrots, broccoli, and dark-green leafy; tomato-based sauce

27411100	Beef with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, tomato-based sauce
27411150	Beef rolls, stuffed with vegetables or meat mixture, tomato-based sauce
27411200	Beef with vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, tomato-based sauce
27420400	Pork and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, tomato-based sauce
27420410	Pork and vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, tomato-based sauce
27420460	Sausage and vegetables, excluding carrots, broccoli, and dark-green leafy; no potatoes, tomato-based sauce
27445125	Chicken or turkey and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, tomato-based sauce
27445130	Chicken or turkey and vegetables excluding carrots, broccoli, and dark-green leafy; no potatoes, tomato-based sauce
27450700	Fish and vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes, tomato-based sauce
27450710	Fish and vegetables excluding carrots, broccoli, and dark- green leafy; no potatoes, tomato-based sauce
27510700	Meatball and spaghetti sauce submarine sandwich
28110150	Beef with vegetable, diet frozen meal
28110390	Salisbury steak, potatoes, vegetable, dessert, diet frozen meal
28141610	Chicken and vegetables in cream or white sauce, diet frozen meal
28143020	Chicken and vegetable entree with rice, diet frozen meal
28143040	Chicken chow mein with rice, diet frozen meal
28143080	Chicken with noodles and cheese sauce, diet frozen meal
28143150	Chicken and vegetable entree with noodles, diet frozen meal
28143180	Chicken in butter sauce with potatoes and vegetable, diet frozen meal
28145100	Turkey with gravy, dressing, vegetable and fruit, diet frozen meal
28154010	Shrimp and vegetables in sauce with noodles, diet frozen meal
28340179	Beef broth, less or reduced sodium, canned or ready-to-serve
28340180	Chicken or turkey broth, less or reduced sodium, canned or ready-to-serve
28355140	Clam chowder, New England, reduced sodium, canned or ready-to-serve
28501010	Gravy, beef, fat free
28501110	Gravy, poultry, fat free
41205050	Bean dip, made with refried beans
41205070	Hummus, plain
41205075	Hummus, flavored
41420350	Soy sauce, reduced sodium
41420410	Teriyaki sauce, reduced sodium
41440000	Textured vegetable protein, dry
41602070	Split pea soup, canned, reduced sodium, prepared with water or ready-to-serve
41810200	Bacon strip, meatless
41810400	Breakfast link, pattie, or slice, meatless
41810600	Chicken, meatless, NFS

41810610	Chicken, meatless, breaded, fried
41811400	Frankfurter or hot dog, meatless
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey
41811800	Meatball, meatless
41811890	Vegetarian burger or patty, meatless, no bun
41811950	Swiss steak, with gravy, meatless
41812000	Sandwich spread, meat substitute type
41812400	Vegetarian pot pie
41812450	Vegetarian chili, made with meat substitute
41812600	Vegetarian, fillet
41812800	Vegetarian stew
41812850	Vegetarian stroganoff
41812900	Vegetarian meat loaf
51000100	Bread, NS as to major flour
51000110	Bread, NS as to major flour, toasted
51000180	Bread, made from home recipe or purchased at a bakery, NS as to major flour
51000200	Roll, NS as to major flour
51101000	Bread, white
51101010	Bread, white, toasted
51101050	Bread, white, made from home recipe or purchased at a bakery
51101060	Bread, white, made from home recipe or purchased at a bakery, toasted
51122000	Bread, reduced calorie and/or high fiber, white or NFS
51122100	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts
51122110	Bread, reduced calorie and/or high fiber, white or NFS, with fruit and/or nuts, toasted
51180010	Bagel
51180030	Bagel, with raisins
51180080	Bagel, with fruit other than raisins
51184100	Breadsticks, hard, reduced sodium
51300110	Bread, whole wheat
51300120	Bread, whole wheat, toasted
51300140	Bread, whole wheat, made from home recipe or purchased at bakery
51300150	Bread, whole wheat, made from home recipe or purchased at bakery, toasted
51300175	Bread, chappatti or roti, wheat
51300180	Bread, puri, wheat
51300185	Bread, paratha, wheat
51300210	Bread, whole wheat, with raisins
51300220	Bread, whole wheat, with raisins, toasted
51300300	Bread, sprouted wheat
51300310	Bread, sprouted wheat, toasted
51301010	Bread, wheat or cracked wheat
51301020	Bread, wheat or cracked wheat, toasted
51301040	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery
51301050	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery, toasted

51301120	Bread, wheat or cracked wheat, with raisins
51301130	Bread, wheat or cracked wheat, with raisins, toasted
51301510	Bread, wheat or cracked wheat, reduced calorie and/or high fiber
51301540	Bread, French or Vienna, whole wheat
51301550	Bread, French or Vienna, whole wheat, toasted
51301600	Bread, pita, whole wheat
51301620	Bread, pita, wheat or cracked wheat
51301700	Bagel, wheat
51301750	Bagel, whole wheat
51301800	Bagel, wheat, with raisins
51301805	Bagel, whole wheat, with raisins
51301820	Bagel, wheat, with fruit and nuts
51302500	Muffin, English, wheat bran
51303010	Muffin, English, wheat or cracked wheat
51303030	Muffin, English, whole wheat
51303050	Muffin, English, wheat or cracked wheat, with raisins
51303070	Muffin, English, whole wheat, with raisins
51320010	Roll, wheat or cracked wheat
51320060	Roll, wheat or cracked wheat, hot dog bun
51320070	Roll, wheat or cracked wheat, hamburger bun
51320500	Roll, whole wheat
51320550	Roll, whole wheat, hot dog bun
51320560	Roll, whole wheat, hamburger bun
51601010	Bread, multigrain, toasted
51601020	Bread, multigrain
51601210	Bread, multigrain, with raisins
51602020	Bread, multigrain, reduced calorie and/or high fiber, toasted
51620000	Roll, multigrain
51620030	Roll, multigrain, hamburger bun
51630000	Bagel, multigrain
51630100	Bagel, multigrain, with raisins
51630200	Muffin, English, multigrain
52104040	Biscuit, wheat
52215200	Tortilla, flour
52215260	Tortilla, whole wheat
52301000	Muffin, NFS
52302010	Muffin, fruit
52302020	Muffin, fruit, low fat
52303010	Muffin, whole wheat
52303500	Muffin, wheat
52304000	Muffin, whole grain
52304010	Muffin, wheat bran
52304040	Muffin, bran with fruit, lowfat
53109220	Snack cake, not chocolate, with icing or filling, reduced fat and calories
53204840	Cookie, brownie, reduced fat, NS as to icing

53204860	Cookie, brownie, fat free, NS as to icing
53206030	Cookie, chocolate chip, reduced fat
53207020	Cookie, chocolate or fudge, reduced fat
53207050	Cookie, chocolate, with chocolate filling or coating, fat free
53209020	Cookie, chocolate sandwich, reduced fat
53220040	Cookie, fig bar, fat free
53233040	Cookie, oatmeal, reduced fat, NS as to raisins
53239010	Cookie, shortbread, reduced fat
53243050	Cookie, vanilla sandwich, reduced fat
53247050	Cookie, vanilla wafer, reduced fat
53260030	Cookie, chocolate chip, sugar free
53260200	Cookie, oatmeal, sugar free
53260300	Cookie, sandwich, sugar free
53260400	Cookie, sugar or plain, sugar free
53260500	Cookie, sugar wafer, sugar free
53260600	Cookie, peanut butter, sugar free
53300100	Pie, NFS
53300170	Pie, individual size or tart, NFS
53530010	Breakfast tart, lowfat
53710800	Cereal or granola bar (Kashi Chewy)
53710802	Cereal or granola bar (Kashi Crunchy)
53711002	Cereal or granola bar (Quaker Chewy 90 Calorie Granola Bar)
53711004	Cereal or granola bar (Quaker Chewy 25% Less Sugar Granola Bar)
53712200	Cereal or granola bar, lowfat, NFS
53712210	Cereal or granola bar, nonfat
53714400	Cereal or granola bar, with rice cereal
53714500	Breakfast bar, NFS
53714520	Breakfast bar, cereal crust with fruit filling, lowfat
53720100	Nutrition bar (Balance Original Bar)
53720200	Nutrition bar (Clif Bar)
53720210	Nutrition bar (Clif Kids Organic Zbar)
53720300	Nutrition bar (PowerBar)
53720400	Nutrition bar (Slim Fast Original Meal Bar)
53720500	Nutrition bar (Snickers Marathon Protein Bar)
53720600	Nutrition bar (South Beach Living Meal Bar)
53720610	Nutrition bar (South Beach Living High Protein Bar)
53720700	Nutrition bar (Tiger's Milk)
53720800	Nutrition bar (Zone Perfect Classic Crunch)
53729000	Nutrition bar or meal replacement bar, NFS
54001000	Crackers, NFS
54102100	Graham crackers, reduced fat
54200100	Crackers, butter, reduced sodium
54201010	Crackers, matzo, reduced sodium
54202020	Crackers, saltine, reduced sodium
54204020	Crackers, wheat, reduced sodium

54204030	Crackers, woven wheat, reduced sodium
54301100	Crackers, butter, reduced fat
54304100	Crackers, cheese, reduced fat
54304110	Crackers, cheese, reduced sodium
54307000	Crackers, matzo
54318500	Rice cake
54319000	Crackers, rice
54319005	Crackers, rice and nuts
54319020	Popcorn cake
54325000	Crackers, saltine
54325010	Crackers, saltine, reduced fat
54325060	Crackers, saltine, multigrain
54326000	Crackers, multigrain
54328110	Crackers, sandwich, reduced fat, peanut butter filled
54336000	Crackers, water
54337010	Crackers, woven wheat
54337020	Crackers, woven wheat, plain (Triscuit)
54337030	Crackers, woven wheat, flavored (Triscuit)
54337060	Crackers, woven wheat, reduced fat
54338000	Crackers, wheat
54338010	Crackers, wheat, plain (Wheat Thins)
54338020	Crackers, wheat, flavored (Wheat Thins)
54338100	Crackers, wheat, reduced fat
54401121	Tortilla chips, reduced fat, plain
54401122	Tortilla chips, reduced fat, flavored
54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
54408000	Pretzels, NFS
54408015	Pretzels, hard, NFS
54408017	Pretzels, hard, plain, lightly salted
54408030	Pretzels, hard, plain, unsalted
54408070	Pretzels, hard, multigrain
54408105	Pretzel chips, hard, plain
54408110	Pretzel chips, hard, flavored
54408190	Pretzels, hard, coated, NFS
54408200	Pretzels, hard, chocolate coated
54408210	Pretzels, hard, white chocolate coated
54408250	Pretzels, hard, yogurt coated
54408290	Pretzels, hard, filled, NFS
54408300	Pretzels, hard, cheese filled
55101015	Pancakes, plain, reduced fat
55105000	Pancakes, buckwheat
55105205	Pancakes, whole grain, reduced fat
55205000	Waffle, whole grain
55211050	Waffle, plain, reduced fat

55212000	Waffle, whole grain, reduced fat
56140100	Pasta, gluten free
56200300	Cereal, cooked, NFS
56200990	Grits, NS as to regular, quick, or instant, NS as to fat
56201000	Grits, NS as to regular, quick, or instant, no added fat
56201040	Grits, NS as to regular, quick, or instant, fat added
56201050	Grits, regular or quick, made with water, NS as to fat
56201051	Grits, regular or quick, made with water, no added fat
56201052	Grits, regular or quick, made with water, fat added
56201055	Grits, regular or quick, made with milk, NS as to fat
56201056	Grits, regular or quick, made with milk, no added fat
56201057	Grits, regular or quick, made with milk, fat added
56201090	Grits, with cheese, NS as to fat
56201091	Grits, with cheese, no added fat
56201092	Grits, with cheese, fat added
56201340	Grits, instant, made with milk, fat added
56201342	Grits, instant, made with milk, no added fat
56201360	Grits, instant, made with non-dairy milk, fat added
56202900	Oatmeal, from fast food, plain
56202905	Oatmeal, from fast food, maple flavored
56202910	Oatmeal, from fast food, fruit flavored
56202920	Oatmeal, from fast food, other flavors
56202960	Oatmeal, NS as to regular, quick, or instant, NS as to fat
56203000	Oatmeal, NS as to regular, quick, or instant, no added fat
56203055	Oatmeal, regular or quick, made with water, NS as to fat
56203056	Oatmeal, regular or quick, made with water, no added fat
56203065	Oatmeal, regular or quick, made with milk, NS as to fat
56203066	Oatmeal, regular or quick, made with milk, no added fat
56203075	Oatmeal, regular or quick, made with non-dairy milk, NS as to fat
56203076	Oatmeal, regular or quick, made with non-dairy milk, no added fat
56203086	Oatmeal, instant, plain, made with water, no added fat
56203096	Oatmeal, instant, plain, made with milk, no added fat
56203106	Oatmeal, instant, plain, made with non-dairy milk, no added fat
56203125	Oatmeal, instant, maple flavored, NS as to fat
56203130	Oatmeal, instant, maple flavored, no added fat
56203150	Oatmeal, instant, fruit flavored, NS as to fat
56203155	Oatmeal, instant, fruit flavored, no added fat
56203175	Oatmeal, instant, other flavors, no added fat
56203510	Oatmeal, reduced sugar, plain, no added fat
56203550	Oatmeal, reduced sugar, flavored, NS as to fat
56203555	Oatmeal, reduced sugar, flavored, no added fat
56203560	Oatmeal, reduced sugar, flavored, fat added
56203600	Oatmeal, multigrain, NS as to fat
56203610	Oatmeal, multigrain, no added fat
56205011	Rice, brown, cooked, NS as to fat

56205012	Rice, brown, cooked, fat added, made with oil
56205014	Rice, brown, cooked, made with butter
56205016	Rice, brown, cooked, made with margarine
56205017	Rice, brown, cooked, fat added, NS as to fat type
56205018	Rice, brown, cooked, no added fat
56207005	Cream of wheat, NS as to regular, quick, or instant, fat added
56207016	Cream of wheat, regular or quick, made with water, no added fat
56207017	Cream of wheat, regular or quick, made with water, fat added
56207022	Cream of wheat, regular or quick, made with milk, no added fat
56207023	Cream of wheat, regular or quick, made with milk, fat added
56207027	Cream of wheat, regular or quick, made with non-dairy milk, fat added
56207030	Cream of wheat, instant, made with water, no added fat
56207060	Cream of wheat, instant, made with water, fat added
56207094	Cream of wheat, instant, made with milk, fat added
56207095	Cream of wheat, instant, made with milk, no added fat
56207102	Cream of wheat, instant, made with non-dairy milk, no added fat
56207200	Whole wheat cereal, cooked, no added fat
56207210	Whole wheat cereal, cooked, fat added
56207370	Wheat cereal, chocolate flavored, cooked
56208500	Oat bran cereal, cooked, no added fat
56208510	Oat bran cereal, cooked, fat added
56208520	Oat bran cereal, cooked, NS as to fat
57000100	Cereal, oat, NFS
57100100	Cereal, ready-to-eat, NFS
57101000	Cereal (Kellogg's All-Bran)
57103000	Cereal (Post Alpha-Bits)
57103100	Cereal (General Mills Cheerios Apple Cinnamon)
57104000	Cereal (Kellogg's Apple Jacks)
57106050	Cereal (Post Great Grains Banana Nut Crunch)
57106060	Cereal (General Mills Cheerios Banana Nut)
57106100	Cereal (General Mills Basic 4)
57106250	Cereal (General Mills Kix Berry Berry)
57106260	Cereal (General Mills Cheerios Berry Burst)
57107000	Cereal (General Mills Boo Berry)
57110000	Cereal (Kellogg's All-Bran Bran Buds)
57117000	Cereal (Quaker Cap'n Crunch)
57117500	Cereal (Quaker Christmas Crunch)
57119000	Cereal (Quaker Cap'n Crunch's Crunchberries)
57120000	Cereal (Quaker Cap'n Crunch's Peanut Butter Crunch)
57123000	Cereal (General Mills Cheerios)
57124030	Cereal (General Mills Chex Chocolate)
57124050	Cereal (General Mills Chex Cinnamon)
57124100	Cereal (General Mills Cheerios Chocolate)
57124200	Cereal, chocolate flavored, frosted, puffed corn
57124300	Cereal (General Mills Lucky Charms Chocolate)

57125000	Cereal (General Mills Cinnamon Toast Crunch)
57125010	Cereal (General Mills 25% Less Sugar Cinnamon Toast Crunch)
57125900	Cereal (General Mills Honey Nut Clusters)
57126000	Cereal (Kellogg's Cocoa Krispies)
57127000	Cereal (Post Cocoa Pebbles)
57128000	Cereal (General Mills Cocoa Puffs)
57128005	Cereal (General Mills 25% Less Sugar Cocoa Puffs)
57130000	Cereal (General Mills Cookie Crisp)
57132000	Cereal (General Mills Chex Corn)
57134000	Cereal, corn flakes
57135000	Cereal (Kellogg's Corn Flakes)
57137000	Cereal, corn puffs
57139000	Cereal (General Mills Count Chocula)
57143000	Cereal (Kellogg's Cracklin' Oat Bran)
57143500	Cereal (Post Great Grains, Cranberry Almond Crunch)
57148000	Cereal (Kellogg's Crispix)
57148500	Cereal, crispy brown rice
57151000	Cereal, crispy rice
57201900	Cereal (General Mills Dora The Explorer)
57206700	Cereal (General Mills Fiber One)
57206710	Cereal (General Mills Fiber One Honey Clusters)
57206715	Cereal (General Mills Fiber One Raisin Bran Clusters)
57207000	Cereal, bran flakes
57208000	Cereal (Kellogg's All-Bran Complete Wheat Flakes)
57209000	Cereal (Post Bran Flakes)
57211000	Cereal (General Mills Frankenberry)
57213000	Cereal (Kellogg's Froot Loops)
57213010	Cereal (Kellogg's Froot Loops Marshmallow)
57213850	Cereal (General Mills Cheerios Frosted)
57214000	Cereal (Kellogg's Frosted Mini-Wheats)
57218000	Cereal (Kellogg's Frosted Krispies)
57221700	Cereal, fruit rings
57221810	Cereal (General Mills Cheerios Fruity)
57223000	Cereal (Post Fruity Pebbles)
57224000	Cereal (General Mills Golden Grahams)
57227000	Cereal, granola
57228000	Granola, homemade
57229000	Cereal (Kellogg's Low Fat Granola)
57229500	Cereal (Kellogg's Low Fat Granola with Raisins)
57230000	Cereal (Post Grape-Nuts)
57231000	Cereal (Post Grape-Nuts Flakes)
57231200	Cereal (Post Great Grains Raisins, Dates, and Pecans)
57231250	Cereal (Post Great Grains Double Pecan Whole Grain Cereal)
57237100	Cereal (Post Honey Bunches of Oats Honey Roasted)
57237200	Cereal (Post Honey Bunches of Oats with Vanilla Bunches)

57237300	Cereal (Post Honey Bunches of Oats with Almonds)
57237900	Cereal (Post Honey Bunches of Oats Just Bunches)
57238000	Cereal (Post Honeycomb)
57240100	Cereal (General Mills Chex Honey Nut)
57241000	Cereal (General Mills Cheerios Honey Nut)
57241200	Cereal (Post Shredded Wheat Honey Nut)
57243000	Cereal (Kellogg's Honey Smacks)
57301500	Cereal (Kashi 7 Whole Grain Puffs)
57301505	Cereal (Kashi Autumn Wheat)
57301510	Cereal (Kashi GOLEAN)
57301511	Cereal (Kashi GOLEAN Crunch)
57301512	Cereal (Kashi GOLEAN Crunch Honey Almond Flax)
57301530	Cereal (Kashi Heart to Heart Honey Toasted Oat)
57303100	Cereal (General Mills Kix)
57303105	Cereal (General Mills Honey Kix)
57303200	Cereal (Kellogg's Krave)
57304100	Cereal (Quaker Life)
57305100	Cereal (General Mills Lucky Charms)
57305150	Cereal, frosted oat cereal with marshmallows
57305160	Cereal (Malt-O-Meal Blueberry Muffin Tops)
57305165	Cereal (Malt-O-Meal Cinnamon Toasters)
57305170	Cereal (Malt-O-Meal Coco-Roos)
57305174	Cereal (Malt-O-Meal Colossal Crunch)
57305175	Cereal (Malt-O-Meal Cocoa Dyno-Bites)
57305180	Cereal (Malt-O-Meal Corn Bursts)
57305200	Cereal (Malt-O-Meal Crispy Rice)
57305210	Cereal (Malt-O-Meal Frosted Flakes)
57305215	Cereal (Malt-O-Meal Frosted Mini Spooners)
57305300	Cereal (Malt-O-Meal Fruity Dyno-Bites)
57305400	Cereal (Malt-O-Meal Honey Graham Squares)
57305500	Cereal (Malt-O-Meal Honey Nut Toasty O's)
57305600	Cereal (Malt-O-Meal Marshmallow Mateys)
57306130	Cereal (Malt-O-Meal Raisin Bran)
57306500	Cereal (Malt-O-Meal Golden Puffs)
57306700	Cereal (Malt-O-Meal Toasted Oat Cereal)
57306800	Cereal (Malt-O-Meal Tootie Fruities)
57307500	Cereal, millet, puffed
57308190	Cereal, muesli
57308400	Cereal (General Mills Cheerios Multigrain)
57309100	Cereal (Nature Valley Granola)
57316300	Cereal (Health Valley Oat Bran Flakes)
57316380	Cereal (General Mills Cheerios Oat Cluster Crunch)
57316385	Cereal (General Mills Cheerios Protein)
57316450	Cereal (General Mills Oatmeal Crisp with Almonds)
57316710	Cereal (Quaker Honey Graham Oh's)

57320500	Cereal (Quaker Granola with Oats, Honey, and Raisins)
57321900	Cereal (Nature's Path Organic Flax Plus)
57326000	Cereal (Barbara's Puffins)
57327450	Cereal (Quaker Toasted Oat Bran)
57327500	Cereal (Quaker Oatmeal Squares)
57329000	Cereal, raisin bran
57330000	Cereal (Kellogg's Raisin Bran)
57330010	Cereal (Kellogg's Raisin Bran Crunch)
57331000	Cereal (Post Raisin Bran)
57332050	Cereal (General Mills Total Raisin Bran)
57332100	Cereal (General Mills Raisin Nut Bran)
57335550	Cereal (General Mills Reese's Puffs)
57336000	Cereal (General Mills Chex Rice)
57337000	Cereal, rice flakes
57339000	Cereal (Kellogg's Rice Krispies)
57339500	Cereal (Kellogg's Rice Krispies Treats Cereal)
57340000	Cereal, puffed rice
57341000	Cereal (Post Shredded Wheat'n Bran)
57341200	Cereal (Kellogg's Smart Start Strong)
57341300	Cereal (Kellogg's Smorz)
57344000	Cereal (Kellogg's Special K)
57344001	Cereal (Kellogg's Special K Blueberry)
57344005	Cereal (Kellogg's Special K Chocolatey Delight)
57344007	Cereal (Kellogg's Special K Low Fat Granola)
57344010	Cereal (Kellogg's Special K Red Berries)
57344015	Cereal (Kellogg's Special K Fruit & Yogurt)
57344020	Cereal (Kellogg's Special K Vanilla Almond)
57344025	Cereal (Kellogg's Special K Cinnamon Pecan)
57347000	Cereal (Kellogg's Corn Pops)
57348000	Cereal, frosted corn flakes
57349000	Cereal (Kellogg's Frosted Flakes)
57355000	Cereal (Post Golden Crisp)
57401100	Cereal, toasted oat
57406100	Cereal (General Mills Total)
57407100	Cereal (General Mills Trix)
57407110	Cereal (General Mills 25% Less Sugar Trix)
57408100	Cereal (Uncle Sam)
57410000	Cereal (Weetabix Whole Grain)
57411000	Cereal (General Mills Chex Wheat)
57412000	Wheat germ, plain
57416000	Cereal, puffed wheat, plain
57416010	Cereal, puffed wheat, sweetened
57417000	Cereal (Post Shredded Wheat)
57418000	Cereal (General Mills Wheaties)
57601100	Wheat bran, unprocessed

57602100	Oats, raw
57602500	Oat bran, uncooked
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust
58101820	Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips
58101830	Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips
58106200	Pizza, cheese, from frozen, thin crust
58106205	Pizza, cheese, from frozen, thick crust
58106210	Pizza, cheese, from restaurant or fast food, NS as to type of crust
58106220	Pizza, cheese, from restaurant or fast food, thin crust
58106225	Pizza, cheese, from restaurant or fast food, medium crust
58106230	Pizza, cheese, from restaurant or fast food, thick crust
58106233	Pizza, cheese, stuffed crust
58106234	Pizza, cheese, from school lunch, medium crust
58106235	Pizza, cheese, from school lunch, thin crust
58106236	Pizza, cheese, from school lunch, thick crust
58106250	Pizza, extra cheese, thin crust
58106260	Pizza, extra cheese, thick crust
58106300	Pizza, cheese, with vegetables, from frozen, thin crust
58106305	Pizza, cheese with vegetables, from frozen, thick crust
58106320	Pizza, cheese, with vegetables, from restaurant or fast food, thin crust
58106325	Pizza, cheese, with vegetables, from restaurant or fast food, medium crust
58106330	Pizza, cheese, with vegetables, from restaurant or fast food, thick crust
58106345	Pizza with cheese and extra vegetables, thin crust
58106347	Pizza with cheese and extra vegetables, medium crust
58106358	Pizza, cheese, with fruit, thin crust
58106359	Pizza, cheese, with fruit, medium crust
58106360	Pizza, cheese, with fruit, thick crust
58106512	Pizza with pepperoni, from frozen, thin crust
58106514	Pizza with pepperoni, from frozen, medium crust
58106516	Pizza with pepperoni, from frozen, thick crust
58106540	Pizza with pepperoni, from restaurant or fast food, NS as to type of crust
58106550	Pizza with pepperoni, from restaurant or fast food, thin crust
58106555	Pizza with pepperoni, from restaurant or fast food, medium crust
58106560	Pizza with pepperoni, from restaurant or fast food, thick crust
58106565	Pizza with pepperoni, stuffed crust
58106570	Pizza with pepperoni, from school lunch, thin crust
58106578	Pizza, with pepperoni, from school lunch, medium crust
58106580	Pizza with pepperoni, from school lunch, thick crust
58106602	Pizza with meat other than pepperoni, from frozen, thin crust
58106604	Pizza with meat other than pepperoni, from frozen, medium crust
58106606	Pizza with meat other than pepperoni, from frozen, thick crust
58106610	Pizza with meat other than pepperoni, from restaurant or fast food, NS as to type of crust

58106620	Pizza with meat other than pepperoni, from restaurant or fast food, thin crust
58106625	Pizza with meat other than pepperoni, from restaurant or fast food, medium crust
58106630	Pizza with meat other than pepperoni, from restaurant or fast food, thick crust
58106633	Pizza, with meat other than pepperoni, stuffed crust
58106634	Pizza, with meat other than pepperoni, from school lunch, medium crust
58106635	Pizza, with meat other than pepperoni, from school lunch, thin crust
58106636	Pizza, with meat other than pepperoni, from school lunch, thick crust
58106650	Pizza with extra meat, thin crust
58106655	Pizza with extra meat, medium crust
58106660	Pizza with extra meat, thick crust
58106700	Pizza with meat and vegetables, from frozen, thin crust
58106702	Pizza with meat and vegetables, from frozen, medium crust
58106705	Pizza with meat and vegetables, from frozen, thick crust
58106720	Pizza with meat and vegetables, from restaurant or fast food, thin crust
58106725	Pizza with meat and vegetables, from restaurant or fast food, medium crust
58106730	Pizza with meat and vegetables, from restaurant or fast food, thick crust
58106736	Pizza with extra meat and extra vegetables, thin crust
58106737	Pizza with extra meat and extra vegetables, thick crust
58106738	Pizza with extra meat and extra vegetables, medium crust
58106750	Pizza with meat and fruit, thin crust
58106755	Pizza with meat and fruit, medium crust
58106760	Pizza with meat and fruit, thick crust
58106830	Pizza with beans and vegetables, thick crust
58107050	Pizza, no cheese, thin crust
58107205	White pizza, cheese, thin crust
58108050	Pizza rolls
58109015	Pizza, cheese, whole wheat thin crust
58109020	Pizza, cheese, whole wheat thick crust
58109030	Pizza, with meat, whole wheat thin crust
58109040	Pizza, with meat, whole wheat thick crust
58109050	Pizza, cheese and vegetables, whole wheat thin crust
58109060	Pizza, cheese and vegetables, whole wheat thick crust
58109100	Pizza, cheese, gluten-free thin crust
58109120	Pizza, with meat, gluten-free thin crust
58109130	Pizza, with meat, gluten-free thick crust
58109140	Pizza, cheese and vegetables, gluten-free thin crust
58109150	Pizza, cheese and vegetables, gluten-free thick crust
58126150	Turnover, meat- and cheese-filled, tomato-based sauce
58126160	Turnover, cheese-filled, tomato-based sauce
58126300	Turnover, meat- and cheese-filled, tomato-based sauce, lower in fat
58130011	Lasagna with meat
58130013	Lasagna with meat, canned
58130014	Lasagna with meat, from restaurant
58130015	Lasagna with meat, home recipe
58130016	Lasagna with meat, frozen

58130020	Lasagna with meat and spinach
58130140	Lasagna with chicken or turkey
58130150	Lasagna, with chicken or turkey, and spinach
58130310	Lasagna, meatless
58130320	Lasagna, meatless, with vegetables
58131110	Ravioli, NS as to filling, with tomato sauce
58131320	Ravioli, meat-filled, with tomato sauce or meat sauce
58131323	Ravioli, meat-filled, with tomato sauce or meat sauce, canned
58131520	Ravioli, cheese-filled, with tomato sauce
58131523	Ravioli, cheese-filled, with tomato sauce, canned
58131610	Ravioli, cheese and spinach filled, with tomato sauce
58133120	Manicotti, cheese-filled, with tomato sauce, meatless
58134120	Stuffed shells, cheese-filled, with tomato sauce, meatless
58134130	Stuffed shells, cheese-filled, with meat sauce
58134310	Stuffed shells, with fish and/or shellfish, with tomato sauce
58134610	Tortellini, meat-filled, with tomato sauce
58134613	Tortellini, meat-filled, with tomato sauce, canned
58134620	Tortellini, cheese-filled, meatless, with tomato sauce
58134710	Tortellini, spinach-filled, with tomato sauce
58145140	Macaroni or noodles with cheese and tomato
58146221	Pasta with tomato-based sauce, restaurant
58146222	Pasta with tomato-based sauce, home recipe
58146223	Pasta with tomato-based sauce, ready-to-heat
58146301	Pasta with tomato-based sauce, and added vegetables, restaurant
58146302	Pasta with tomato-based sauce, and added vegetables, home recipe
58146303	Pasta with tomato-based sauce, and added vegetables, ready-to-heat
58146321	Pasta with tomato-based sauce and meat, restaurant
58146322	Pasta with tomato-based sauce and meat, home recipe
58146323	Pasta with tomato-based sauce and meat, ready-to-heat
58146331	Pasta with tomato-based sauce, meat, and added vegetables, restaurant
58146332	Pasta with tomato-based sauce, meat, and added vegetables, home recipe
58146333	Pasta with tomato-based sauce, meat, and added vegetables, ready-to-heat
58146341	Pasta with tomato-based sauce and poultry, restaurant
58146342	Pasta with tomato-based sauce and poultry, home recipe
58146343	Pasta with tomato-based sauce and poultry, ready-to-heat
58146351	Pasta with tomato-based sauce, poultry, and added vegetables, restaurant
58146352	Pasta with tomato-based sauce, poultry, and added vegetables, home recipe
58146353	Pasta with tomato-based sauce, poultry, and added vegetables, ready-to-heat
58146361	Pasta with tomato-based sauce and seafood, restaurant
58146362	Pasta with tomato-based sauce and seafood, home recipe
58146363	Pasta with tomato-based sauce and seafood, ready-to-heat
58146371	Pasta with tomato-based sauce, seafood, and added vegetables, restaurant
58146372	Pasta with tomato-based sauce, seafood, and added vegetables, home recipe
58146373	Pasta with tomato-based sauce, seafood, and added vegetables, ready-to-heat
58146601	Pasta, whole grain, with tomato-based sauce, restaurant

58146602	Pasta, whole grain, with tomato-based sauce, home recipe
58146603	Pasta, whole grain, with tomato-based sauce, ready-to-heat
58146612	Pasta, whole grain, with tomato-based sauce and added vegetables, home recipe
58146613	Pasta, whole grain, with tomato-based sauce and added vegetables, ready-to-heat
58146622	Pasta, whole grain, with tomato-based sauce and meat, home recipe
58146623	Pasta, whole grain, with tomato-based sauce and meat, ready-to-heat
58146632	Pasta, whole grain, with tomato-based sauce, meat, and added vegetables, home recipe
58146641	Pasta, whole grain, with tomato-based sauce and poultry, restaurant
58146642	Pasta, whole grain, with tomato-based sauce and poultry, home recipe
58146652	Pasta, whole grain, with tomato-based sauce, poultry, and added vegetables, home recipe
58146653	Pasta, whole grain, with tomato-based sauce, poultry, and added vegetables, ready-to-heat
58146662	Pasta, whole grain, with tomato-based sauce and seafood, home recipe
58146672	Pasta, whole grain, with tomato-based sauce, seafood, and added vegetables, home recipe
58160520	Rice, white, with tomatoes and/or tomato-based sauce, NS as to fat
58160530	Rice, white, with tomatoes and/or tomato-based sauce, no added fat
58160540	Rice, white, with tomatoes and/or tomato-based sauce, fat added
58160580	Rice, white, with carrots and tomatoes and/or tomato-based sauce, NS as to fat
58160600	Rice, white, with carrots and tomatoes and/or tomato-based sauce, fat added
58160610	Rice, white, with dark green vegetables and tomatoes and/or tomato-based sauce, NS as to fat
58160620	Rice, white, with dark green vegetables and tomatoes and/or tomato-based sauce, no added fat
58160630	Rice, white, with dark green vegetables and tomatoes and/or tomato-based sauce, fat added
58160670	Rice, white, with carrots, dark green vegetables, and tomatoes and/or tomato-based sauce, NS as to fat
58160690	Rice, white, with carrots, dark green vegetables, and tomatoes and/or tomato-based sauce, fat added
58161460	Rice, brown, with tomatoes and/or tomato based sauce, NS as to fat
58161462	Rice, brown, with tomatoes and/or tomato based sauce, no added fat
58161464	Rice, brown, with tomatoes and/or tomato based sauce, fat added
58161480	Rice, brown, with carrots and tomatoes and/or tomato-based sauce, NS as to fat
58161490	Rice, brown, with dark green vegetables and tomatoes and/or tomato-based sauce, NS as to fat
58161524	Rice, brown, with carrots, dark green vegetables, and tomatoes and/or tomato-based sauce, fat added
58163310	Flavored rice mixture
58163330	Flavored rice mixture with cheese
58163360	Flavored rice, brown and wild
58163380	Flavored rice and pasta mixture
58163405	Spanish rice, from restaurant

58163410	Spanish rice, fat added
58163420	Spanish rice, no added fat
58163430	Spanish rice, NS as to fat
58163450	Spanish rice with ground beef
58163510	Rice dressing
58164110	Rice with raisins
58301050	Lasagna with cheese and meat sauce, diet frozen meal
58302000	Macaroni and cheese, diet frozen meal
58302050	Beef and noodles with meat sauce and cheese, diet frozen meal
58302080	Noodles with vegetables in tomato-based sauce, diet frozen meal
58304060	Spaghetti with meat sauce, diet frozen meal
58304200	Ravioli, cheese-filled, with tomato sauce, diet frozen meal
58305250	Pasta with vegetable and cheese sauce, diet frozen meal
58306100	Chicken enchilada, diet frozen meal
58403060	Chicken or turkey noodle soup, reduced sodium, canned or ready-to-serve
58404040	Chicken or turkey rice soup, reduced sodium, canned, prepared with water or ready-to-serve
58407010	Instant soup, noodle
58407030	Soup, mostly noodles
58407035	Soup, mostly noodles, reduced sodium
59003000	Meat substitute, cereal- and vegetable protein-based, fried
62101000	Fruit, dried, NFS, uncooked
62101050	Fruit mixture, dried
62101100	Apple, dried
62101230	Apple, dried, cooked, with sugar
62101300	Apple chips
62104100	Apricot, dried
62104220	Apricot, dried, cooked, unsweetened
62105000	Blueberries, dried
62106000	Cherries, dried
62107200	Banana chips
62108100	Currants, dried
62109100	Cranberries, dried
62110100	Date
62113100	Fig, dried
62114050	Mango, dried
62114110	Papaya, dried
62116100	Peach, dried
62119100	Pear, dried
62120000	Persimmon, dried
62120100	Pineapple, dried
62121100	Plum, rock salt, dried
62122100	Prune, dried
62122200	Prune, dried, cooked, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener

62122220	Prune, dried, cooked, unsweetened
62125100	Raisins
62125110	Raisins, cooked
62126000	Tamarind, dried
63100110	Fruit, pickled
63101000	Apple, raw
63101110	Applesauce, regular
63101120	Applesauce, unsweetened
63101150	Applesauce, flavored
63101210	Apple pie filling
63101310	Apple, baked
63101320	Apple, baked, unsweetened
63101330	Apple, baked, with sugar
63135120	Peach, cooked or canned, unsweetened, water pack
63135130	Peach, cooked or canned, in heavy syrup
63135140	Peach, canned, in syrup
63135150	Peach, cooked or canned, drained solids
63135170	Peach, canned, juice pack
63137120	Pear, cooked or canned, unsweetened, water pack
63137130	Pear, cooked or canned, in heavy syrup
63137140	Pear, canned, in syrup
63137150	Pear, cooked or canned, drained solids
63137170	Pear, canned, juice pack
63141110	Pineapple, canned, NFS
63141120	Pineapple, cooked or canned, unsweetened, waterpack
63141130	Pineapple, cooked or canned, in heavy syrup
63141140	Pineapple, canned, in syrup
63141150	Pineapple, cooked or canned, drained solids
63141170	Pineapple, canned, juice pack
63141200	Pineapple, frozen
63207000	Cranberries, NS as to raw, cooked, or canned
63409010	Guacamole, NFS
63409015	Guacamole with tomatoes
63409020	Chutney
63420105	Frozen fruit juice bar
63420110	Fruit juice bar, frozen, flavor other than orange
63420205	Frozen fruit juice bar, no sugar added
63430100	Sorbet, fruit, noncitrus flavor
63430150	Sorbet
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice
64100200	Cranberry juice blend, 100% juice
64100220	Cranberry juice blend, 100% juice, with calcium added
74301100	Tomato juice, 100%
74302000	Tomato juice cocktail

74303000	Tomato and vegetable juice, 100%
74303100	Tomato and vegetable juice, 100%, low sodium
74401010	Ketchup
74406010	Barbecue sauce
74406100	Steak sauce
75506100	Honey mustard dip
75607090	Mushroom soup, cream of, canned, reduced sodium, NS as to made with milk or water
75607100	Mushroom soup, cream of, canned, reduced sodium, prepared with milk
75607140	Mushroom soup, cream of, canned, reduced sodium, prepared with water
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75650990	Minestrone soup, reduced sodium, canned or ready-to-serve
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
83200100	Salad dressing, light, NFS
83201000	Blue or roquefort cheese dressing, light
83203000	Caesar dressing, light
83204000	Mayonnaise, light
83204030	Mayonnaise, reduced fat, with olive oil
83204050	Mayonnaise-type salad dressing, light
83204500	Honey mustard dressing, light
83205450	Italian dressing, light
83206500	Sesame dressing, light
83207000	Thousand Island dressing, light
83300100	Blue or roquefort cheese dressing, fat free
83300200	Caesar dressing, fat free
83300500	Honey mustard dressing, fat free
83300600	Italian dressing, fat free
83300700	Mayonnaise, fat free
83300900	Salad dressing, fat free, NFS
83301000	Thousand Island dressing, fat free
91501010	Gelatin dessert
91511010	Gelatin dessert, sugar free
91511020	Gelatin dessert, sugar free, with fruit
91511030	Gelatin dessert, dietetic, with whipped topping, sweetened with low calorie sweetener
91511060	Gelatin dessert, dietetic, with sour cream, sweetened with low calorie sweetener
91611100	Popsicle, no sugar added
91700010	Candy, NFS
91703080	Caramel, all flavors, sugar free
91708100	Fruit snacks candy, with high vitamin C
91770010	Dietetic or low calorie gumdrops
91770020	Dietetic or low calorie hard candy
91770030	Dietetic or low calorie candy, chocolate covered
92100000	Coffee, NS as to type

92100500	Coffee, NS as to brewed or instant
92101000	Coffee, brewed
92101500	Coffee, brewed, blend of regular and decaffeinated
92101610	Coffee, espresso
92101630	Coffee, espresso, decaffeinated
92101700	Coffee, brewed, flavored
92101800	Coffee, Cuban
92101810	Coffee, macchiato
92101820	Coffee, macchiato, sweetened
92101850	Coffee, cafe con leche
92101851	Coffee, cafe con leche, decaffeinated
92101900	Coffee, Latte
92101901	Coffee, Latte, nonfat
92101903	Coffee, Latte, with non-dairy milk
92101904	Coffee, Latte, flavored
92101905	Coffee, Latte, nonfat, flavored
92101906	Coffee, Latte, with non-dairy milk, flavored
92101910	Coffee, Latte, decaffeinated
92101911	Coffee, Latte, decaffeinated, nonfat
92101917	Coffee, Latte, decaffeinated, flavored
92101918	Coffee, Latte, decaffeinated, nonfat, flavored
92101950	Coffee, Cafe Mocha
92101955	Coffee, Cafe Mocha, nonfat
92101960	Coffee, Cafe Mocha, with non-dairy milk
92101965	Coffee, Cafe Mocha, decaffeinated
92101975	Coffee, Cafe Mocha, decaffeinated, with non-dairy milk
92102400	Iced Coffee, brewed
92102401	Iced Coffee, brewed, decaffeinated
92102450	Iced Coffee, pre-lightened and pre-sweetened
92102500	Coffee, Iced Latte
92102501	Coffee, Iced Latte, nonfat
92102502	Coffee, Iced Latte, with non-dairy milk
92102503	Coffee, Iced Latte, flavored
92102505	Coffee, Iced Latte, with non-dairy milk, flavored
92102600	Coffee, Iced Cafe Mocha
92102602	Coffee, Iced Cafe Mocha, with non-dairy milk
92161000	Coffee, Cappuccino
92161001	Coffee, Cappuccino, nonfat
92161002	Coffee, Cappuccino, with non-dairy milk
92162000	Coffee, Cappuccino, decaffeinated
92162001	Coffee, Cappuccino, decaffeinated, nonfat
92191100	Coffee, instant, not reconstituted
92191200	Coffee, instant, decaffeinated, not reconstituted
92306000	Tea, hot, herbal
92410110	Carbonated water, sweetened

92410210	Carbonated water, unsweetened
92410250	Carbonated water, sweetened, with low-calorie or no-calorie sweetener
92432000	Fruit juice drink, citrus, carbonated
92433000	Fruit juice drink, noncitrus, carbonated
92512040	Frozen daiquiri mix, frozen concentrate, not reconstituted
92530510	Cranberry juice drink, with high vitamin C
92530610	Fruit juice drink, with high vitamin C
92530950	Vegetable and fruit juice drink, with high vitamin C
92531030	Fruit juice drink (Sunny D)
92542000	Fruit flavored drink, with high vitamin C, powdered, reconstituted
92550030	Fruit juice drink, with high vitamin C, light
92550035	Fruit juice drink, light
92550040	Fruit juice drink, diet
92550110	Cranberry juice drink, with high vitamin C, light
92550350	Orange juice beverage, 40-50% juice, light
92550360	Apple juice beverage, 40-50% juice, light
92550610	Fruit flavored drink, with high vitamin C, diet
92550620	Fruit flavored drink, diet
92552020	Fruit juice drink, reduced sugar (Sunny D)
92582100	Fruit juice drink, with high vitamin C, plus added calcium
92582110	Fruit juice drink, added calcium (Sunny D)
93102000	Beer, light
93102100	Beer, low carb
93102200	Beer, light, higher alcohol
94100100	Water, bottled, unsweetened
94100200	Water, bottled, sweetened, with low calorie sweetener
94220215	Water, bottled, flavored, sugar free (Glaceau Vitamin Water)
94220310	Water, bottled, flavored, sugar free (SoBe)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE (Subpart E of Part 170)

Form Approved: OMB No. 0910-0342; Expiration Date: 07/31/2022
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration,5001 Campus Drive, College Park, MD 20740-3835.

SECTION A – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☒ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3 Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd):* 2021-12-20

4 For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd):* _____

SECTION B – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position or Title
Steve Prancevic	Vice President

Organization *(if applicable)*: Anderson Global Group

Mailing Address *(number and street)*: 2030 Main Street

City	State or Province	Zip Code/Postal Code	Country
Irvine	California	92614	United States of America

Telephone Number	Fax Number	E-Mail Address
9495024770		stevep@andersonglobalgroup.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position or Title
Susan Cho	Chief Science Officer

Organization *(if applicable)*: AceOne RS

Mailing Address *(number and street)*: 6309 Morning Dew Ct, Suite 101

City	State or Province	Zip Code/Postal Code	Country
Clarksville	Maryland	21029	

Telephone Number	Fax Number	E-Mail Address
3018756454		scho@aceoners.com

SECTION C – GENERAL ADMINISTRATIVE INFORMATION

1. Name of notified substance, using an appropriately descriptive term

Resistant dextrin; it is derived from tapioca starch

2. Submission Format: *(Check appropriate box(es))*

☒ Electronic Submission Gateway

☐ Electronic files on physical media

☐ Paper

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

4. Does this submission incorporate any information in CFSAN's files? *(Check one)*

☒ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates information from a previous submission to FDA as indicated below *(Check all that apply)*

☒ a) GRAS Notice No. GRN 000436

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

☐ e) Other or Additional *(describe or enter information as above)* _____

6. Statutory basis for conclusions of GRAS status *(Check one)*

☒ Scientific procedures *(21 CFR 170.30(a) and (b))* ☐ Experience based on common use in food *(21 CFR 170.30(a) and (c))*

7. Does the submission (including information that you are incorporating) contain information that you view as trade secret or as confidential commercial or financial information? (see 21 CFR 170.225(c)(8))

☐ Yes *(Proceed to Item 8*

☒ No *(Proceed to Section D)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

SECTION D – INTENDED USE

1. Describe the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance.

Resistant dextrin will be used as a food ingredient. The intended use levels will be 1.2 to 10 g/serving in 17 food categories. Intended use is similar to those described in GRN 436 for most of the food categories except a newly added category of nutrition bar at 10 g/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; (16) dry beverage powder; and (17) nutrition bars. The population expected to consume the substance consists of members of the general population

h l f h d d b d b

2. Does the intended use of the notified substance include any use in product(s) subject to regulation by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture?

(Check one)

☐ Yes ☒ No

3. If your submission contains trade secrets, do you authorize FDA to provide this information to the Food Safety and Inspection Service of the U.S. Department of Agriculture?

(Check one)

☐ Yes ☐ No , you ask us to exclude trade secrets from the information FDA will send to FSIS.

SECTION E – PARTS 2 -7 OF YOUR GRAS NOTICE

(check list to help ensure your submission is complete – PART 1 is addressed in other sections of this form)

☒ PART 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect (170.230).

☒ PART 3 of a GRAS notice: Dietary exposure (170.235).

☒ PART 4 of a GRAS notice: Self-limiting levels of use (170.240).

☒ PART 5 of a GRAS notice: Experience based on common use in foods before 1958 (170.245).

☒ PART 6 of a GRAS notice: Narrative (170.250).

☒ PART 7 of a GRAS notice: List of supporting data and information in your GRAS notice (170.255)

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☐ Yes ☒ No

Did you include this other information in the list of attachments?

☐ Yes ☐ No

SECTION F – SIGNATURE AND CERTIFICATION STATEMENTS

1. The undersigned is informing FDA that Anderson Global Group

(name of notifier)

has concluded that the intended use*(s)* of Resistant Dextrin

(name of notified substance)

described on this form, as discussed in the attached notice, is (are) not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is generally recognized as safe recognized as safe under the conditions of its intended use in accordance with § 170.30.

2. Steve Prancevic *(name of notifier)* agrees to make the data and information that are the basis for the conclusion of GRAS status available to FDA if FDA asks to see them; agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so; agrees to send these data and information to FDA if FDA asks to do so.

2030 Main Street, Irvine, CA 92614

(address of notifier or other location)

The notifying party certifies that this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, pertinent to the evaluation of the safety and GRAS status of the use of the substance.The notifying party certifies that the information provided herein is accurate and complete to the best or his/her knowledge. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
	Steve Prancevic, Vice President	12/20/2021

SECTION G – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Form3667.pdf	Administrative
	ResistantDextrinGRAS12-20-2021FinalsubmitedtoFDA.pdf	Administrative

OMB Statement: Public reporting burden for this collection of information is estimated to average 170 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,Food and Drug Administration, Office of Chief Information Officer, PRAStaff@fda.hhs.gov. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

From: Kampmeyer, Christopher
To: sscho397@yahoo.com
Subject: Regarding your submission to FDA"s GRAS Notification Program
Date: Tuesday, February 8, 2022 2:02:00 PM
Attachments: image013.png
image014.png
image015.png
image016.png
image017.png
image018.png

Dear Dr. Cho:

I am writing regarding your submission dated December 20, 2021, regarding uses of “resistant dextrin from tapioca” in food to the GRAS Notification Program. During our prefiling evaluation, we noted that the report in Annex A (Page 53) is identified as “confidential.” Could you please clarify whether this information is in fact confidential or not, in response to this email? We also noted that Part 1 of the notice is missing a signature; there is only what appears to be a typed name in a different font (on page 8). Could you please provide a copy of just this one page with a real signature, in response to this email?

Thank you,
Chris

Chris Kampmeyer, M.S.
Regulatory Review Scientist

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
christopher.kampmeyer@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Susan Cho
To: Kampmeyer, Christopher
Subject: [EXTERNAL] AGG"s Submission to FDA GRAS notice (Resistant Dextrin)
Date: Wednesday, February 9, 2022 8:13:55 PM
Attachments: Resistant Dextrin page 8 with signature 2-9-2022.pdf

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CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Mr. Kampmeyer,

Thank you for your email. Nothing should be confidential.
Please ignore the word 'confidential'.
Please see a revised page 8 with a real signature. We apologize for the inconvenience associated with these matters. Thank you for everything.

Regards,
Susan
Susan Cho, Ph.D.
AceOne RS
6309 Morning Dew Ct. Clarksville, MD 21029
+1-410-531-3336 (O) +1-301-875-6454 (C)

From:	Martin Celia
To:	Kampmeyer, Christopher
Subject:	[EXTERNAL] RE: Regarding your submission to FDA"s GRAS Notification Program
Date:	Wednesday, February 9, 2022 3:33:37 AM
Attachments:	image001.png image002.png image003.png image004.png image005.png image006.png image007.png 2022 (02-09) GRAS signed statement.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Mr.Kampmeyer

Please, find attached the statement. Please let me know if I need to provide anything else.
Many thanks

Best regards

Celia MARTIN, Ph.D
Regulatory Affairs Director
LALLEMAND BIO-INGREDIENTS
Cell : + 34 645 134 980 | cmartin@lallemand.com | www.bio-lallemand.com

From: Kampmeyer, Christopher <Christopher.Kampmeyer@fda.hhs.gov>
Sent: mardi 8 février 2022 20:10
To: Martin Celia <cmartin@lallemand.com>
Subject: Regarding your submission to FDA's GRAS Notification Program

Dear Dr. Martin:

I am writing regarding your submission dated December 21, 2021, regarding uses of "Lipase produced by *Saccharomyces cerevisiae* expressing the gene from *Fusarium oxysporum*" in food to the GRAS Notification Program. During our initial review, we noted that Part 1 of the notice is missing a required statement. Could you please provide a statement, in response to this email, that the notifier is submitting the notice in accordance with Subpart E (per 21 CFR 170.225(c)(1))?

Thank you,

Chris

Chris Kampmeyer, M.S.
Regulatory Review Scientist

Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
christopher.kampmeyer@fda.hhs.gov

Lallemand Inc.
1620 Prefontaine Street
H1W 2N8, Montreal, QC
Canada

To the attention of
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Subject: A lipase from *Fusarium oxysporum* produced by *Saccharomyces cerevisiae* is Generally Recognized As Safe for Use in Baking

To whom it may concern,

§170.225(c)(1) – Submission of GRAS notice

The notifier, Lallemand Inc. (1620 Prefontaine Street H1W 2N8, Montreal, QC, Canada), hereby confirms that the submission of the GRAS (Generally Recognized as Safe) notice regarding uses of "Lipase produced by *Saccharomyces cerevisiae* expressing the gene from *Fusarium oxysporum*" in food is in accordance with subpart E of part 170 of the Code of Federal Regulations.

Celia Martin, PhD
Regulatory Affairs Director
Lallemand Inc.
February 9, 2022

May 27, 2022

To: Dr. Jianrong (Janet) Zhang, FDA

Subject: GRN 1045, Resistant Dextrin: Amendment

From: Susan Cho, AceOne RS

Dear Dr. Zhang,

In response to the second FDA questions, Anderson Global Group (AGG) has prepared its amendment as follow:

1) *The intended use of the notified substance, resistant dextrin from tapioca, is at maximum levels in the range of 1.2 to 10 g per serving in a variety of foods. The notifier describes two formulations of resistant dextrin that include powder and syrup forms with different compositions (e.g. fiber content is ≥80 or ≥60%, respectively).*

   Please clarify whether the intended use levels are on the basis of the fiber constituent or for the whole preparations.

   AGG's Response

   It was based on resistant dextrin powder. In the case of syrups, intended use levels are approximately 32% higher than those described for powder because the solid content of powder and syrup are approximately 95% and 78%, respectively. To be conservative, intended use levels of syrup will be 30% higher than those described for the powder.

   A revised Table 1 is shown below.

Table 1. Intended Use and Maximum Use Levels of Resistant Dextrin % (w/w)

Food category	Maximum use level, g/serving		RACC[a], g
	Powder	Syrup	
Baked goods	3	3.9	15-140
Beverages, liquid non-dairy	3	3.9	36-360
Cereals and granola bars	6	7.8	15-60 (dry); 234-256 (cooked)
Nutrition bars	10	13	50
Condiments and dressings	3	13	5-60
Confections	1.2[b]-3	1.56-3.9	15-30 except dietetic mint (2 g/RACC)
Dairy beverages	3	3.9	15-250

Dairy non-beverages	3	3.9	5-170
Dry beverage powder	1.2[b]-9	1.56-11.7	1.4 -360[b]
Frozen desserts	3	3.9	85-213
Gravies and sauces	3	3.9	30-125
Meal replacements	3	3.9	20-248
Pasta and grain products	3	3.9	91-248
Prepared meals and soups	3	3.9	7-254
Processed fruits	3	3.9	40-140
Shelf-stable desserts	3	3.9	113.5-133.5
Snacks and crackers	3	3.9	30-232

[a]Based on the Reference Amounts Customarily Consumed (RACC) Per Eating Occasion (21 CFR §101.12) (FDA, 2016b; revised in FDA, 2020).
[b]Some of these food codes designate that the beverage is reconstituted with RACC values around 360 g for some types of drinks and around 240 g for some other types of drinks. Some of the food codes are just the powder and are not reconstituted.

2) *The notifier states that based on published information (Trithavisup et al., 2021), resistant tapioca dextrin is composed of α-1,4 (37-48%), α-1,6 (16-21%), and α-1-2 (2.7-4.1%), and βlinkages (26-31%), and AGG states that the composition of their resistant tapioca dextrin is comparable. However, the notifier provides the results of an analysis of the composition of glycosidic linkages in Annex B of the notice, which includes T-Glc (52.3%), 1,3-glc (7.3%), 1,2-glc (4.2%), 1,6-glc (18.4%), 1,4-glc (12.6%), as well as minor amounts of others (1,2,3-glc, 1,2,4-glc, etc.)*

Please discuss how the data in Annex B compares to the published information described in the notice.

o A minor clarification: please confirm that the citation to Trithavisup et al., 2021 in the notice (below) should be 2022 (https://doi.org/10.1016/j.foodchem.2021.130876) Trithavisup K, Shi YC, Krusong K, Tananuwong K. Molecular structure and properties of cassava-based resistant maltodextrins. Food Chem. 2021;369:130876.

AGG's Response

Linkages

According to Trithavisup et al. (2022), α- and β-linkages contribute 55.7-73.1%, and 26-31% of total glycosidic linkages, respectively. AGG's resistant dextrin consists of 67.7% and 32.3% of α- and β-linkages, respectively. Thus, it is summarized that the glycosidic linkage composition of AGG's resistant dextrin-tapioca is comparable to the values reported in the literature (Trithavisup et al., 2022).

As far as we understand, Purdue University is the only American food laboratory which can analyze linkage types. Further breakdown into 1,2-, 1,3- , 1-4, and 1,6-linkgages was

not available in that lab. Thus, AGG presented the detailed linkage types analyzed by Trithavisup et al. (2022) as corroborative data.

Citation for Trithavisup et al.

Thank you for the agency's correction.
The correct citation should be as follows:
Trithavisup K, Shi YC, Krusong K, Tananuwong K. Molecular structure and properties of cassava-based resistant maltodextrins. Food Chem. 2022;369:130876.

3) *We note that in comparison with specifications provided in GRN 000436 (enzyme modified dextrin) and in the Food Chemicals Codex monograph for dextrin, AGG's specifications for resistant tapioca dextrin do not include limits for mono-and di-saccharides or reducing sugars, chloride, sulfur dioxide, or ash. Please discuss why limits for these constituents are unnecessary. We note that for the batch analyses reported in Tables 5 and 6 of the notice, data is included on measured levels of ash, protein, fat, and sugars although no limits are specified for these analytes.*

AGG's Response

The following describes why no limits are specified for the noted analytes:

Sulfur dioxide: No sulfur dioxide is used during the manufacturing process which employs extensive purification process.

Sugars and chloride: The manufacturing process involves extensive purification steps, thus, most of the sugars and chloride are expected to be eliminated. Although chloride was not analysed, it is expected that residual chloride content is minimal as an ion chromatography step employed during the manufacturing process can remove anions. An average of total sugars (mono-and disaccharides) content was 0.73%, thus, the presence of residual sugars would not have an impact on the relative amount of sugars consumed via the diet as an average American's added sugar intake (excluding naturally occurring sugars present in foods, such as from fruits) is approximately 61 g/person/day (Dietary Guidelines for Americans, 2020-2025; pages 41- 43).

Fat and protein: Certificate analysis of 3 non-consecutive batches of resistant starch (tapioca) consistently showed that fat and protein levels were below detection limit of each assay. In addition, raw material, tapioca starch contains trivial amounts of fat and protein (0.02% fat and 0.19% protein; https://fdc.nal.usda.gov/fdc-app.html#/food-details/169717/nutrients).

Reducing sugars: Glucose polymers, such as starch, and its derivatives, such as maltodextrin and dextrin, begin with a reducing sugar, a free aldehyde. When starch is partially hydrolyzed into glucose, it contains more reducing sugars per gram because glucose itself is a reducing sugar. The percentage of reducing sugars present in these starch derivatives, i.e., digestible carbohydrates, is called dextrin equivalent (DE). This is part of the specifications for dextrin as it indicates the degree of hydrolysis of starch into glucose syrup (the higher the DE, the more sugars and less dextrins are present). However, DE may not be relevant for a dietary fiber ingredient, such as resistant dextrin, which consists of mostly non-digestible carbohydrates as it is not likely that dietary fiber is hydrolyzed into glucose during processing or in the human upper gastrointestinal tract. Thus, DE (or reducing sugar) is not part of specifications for most dietary fiber ingredients.

Ash: The ash content in both resistant dextrin powder and syrups are below or near the detection limit of the assay. In addition, ash content of tapioca starch is 0.11% (https://fdc.nal.usda.gov/fdc-app.html#/food-details/169717/nutrients).

Based on the reasons described above, AGG believes that specifications for sulfur dioxide, total sugars (the sum of mono-and di-saccharides), reducing sugars, chloride, sulfur dioxide, or ash are not required for resistant dextrin.

4) *We note that the stability of the notified substances (resistant dextrin powder and syrup) is not discussed in your notice. Please provide a discussion of the stability of resistant dextrin, including any studies of stability conducted with the resistant dextrin powder and syrup produced by the method described in the notice.*

AGG's Response

Assessment of stability was conducted for both powder and syrup forms of resistant dextrin. The purpose of this study was to determine the maximum period of storage at room temperature by evaluating the effects of storage time on meeting specifications, in particular, total dietary fiber content. Resistant dextrin powder and syrup were stored under ambient corporate office conditions (between 24°C and 25°F and a relative humidity not exceeding 75%). Dietary fiber, moisture content, pH, coliform, and yeast and mold counts were evaluated in a few non-consecutive batches of both powder and syrup samples. Shelf stability data are summarized in the tables below.

The dietary fiber content of the powders ranged from 81.6 to 84.2% after 24 months, meeting the specification of > 80% total dietary fiber. In addition, the sample which had been stored for 6 years met the specification of >80% of total dietary fiber. These results support the two-year shelf life of the resistant dextrin powder.

The resistant dextrin syrup complies with the described product specifications (>60% total dietary fiber) up to two years in storage. The stability study showed that the product remained within the prescribed specifications when stored at room temperature for up to 2 years. It should be noted that pH decreased during the storage period; however, the total dietary fiber values were still within specifications.

In summary, these results confirm that resistant dextrin is stable, and the product quality is maintained during a long storage period: a minimum of 24 months for a powder form and a minimum of 12 months for a syrup form.

Powders

	Lot number	Total dietary fiber	Moisture	pH	Coliform	Yeasts and molds
~ 1 year	20210513037	84.6%	5.29%	4.69	< 10 cfu/g	< 10 cfu/g
	20210514027	81.1%	5.39%	4.71	< 10 cfu/g	< 10 cfu/g
	20210511037	85.1%	5.76%	4.60	< 10 cfu/g	< 10 cfu/g
~2 year	20200402037	84.2%	6.12%	4.72	< 10 cfu/g	< 10 cfu/g
	20200622037	81.6%	6.12%	4.39	< 10 cfu/g	< 10 cfu/g
~ 3 years	20191007034	82.5%	6.47%	4.22	< 10 cfu/g	< 10 cfu/g
~ 6 years	20160905024	80.4%	8.06%	4.59	< 10 cfu/g	< 10 cfu/g

Syrups

	Lot Number	Total dietary fiber	Moisture	pH	Coliform	Yeasts and molds
~1 year	20210527033	65.6%	26.32%	4.13	< 10 cfu/g	< 10 cfu/g
	20210504013	64.6%	26.49%	4.10	< 10 cfu/g	< 10 cfu/g
	20210504023	68.2%	26.77%	4.09	< 10 cfu/g	< 10 cfu/g
~ 1.5 years	20201011023	65.0%	26.38%	3.93	< 10 cfu/g	< 10 cfu/g
	20201008033	67.3%	26.33%	3.73	< 10 cfu/g	< 10 cfu/g
~2 years	20200905023	64.5%	25.89%	3.83	< 10 cfu/g	< 10 cfu/g

AGG's data are consistent with stability data of other dietary fiber ingredients. For example, GRN 610 (FDA, 20) describes shelf stability of isomaltodextrin powder which is composed of approximately 83% dietary fiber. Isomaltodextrin (IMD) powder is enzymatically produced from starch derived from corn, cassava, etc. IMD is comprised of only a-D-glucose; 7% of α-1 glucosidic linkages (nonreducing end group), 3% of a-1 ,3, 19% of a-1 ,4, 49% of a-1 ,6, 7% of a-1 ,3,6, and 5% of a-1,4,6 glucosidic linkages. Although the linkage compositions are somewhat different, the dietary fiber content of

IMD and resistant dextrin are comparable. Thus, shelf stability of isomaltodextrin can be used as corroborative data when evaluating the storage stability of resistant dextrin. At an ambient condition (25°C and 60% relative humidity), isomaltodextrin was stable for 24 months (GRN 610: pages 33-36).

GRN 1006 describes the stability study for dry short chain fructooligosaccharides (scFOS; >95% dietary fiber). Powder was stable for 24-months at 25°C and 33% relative humidity (GRN 1006, amendment dated Oct 8, 2021, pages 3-4). Measurement included scFOS content, moisture and microbiology parameters such as total plate counts (or standard plate counts) and coliform. In the case of liquid scFOS, as of October 2021, the stability data were available for up to a 9-month time point. Liquid samples were stable for 9 months, the longest time point tested.

Taken together, similar to other currently marketed dietary fiber products, AGG considers the finished resistant dextrin ingredients to also be stable when kept under ambient conditions for a minimum of 1 year for syrup, and 2 years for powder.

References

FDA, 2016. GRN 610, Isomaltodextrin. Hayashibara Co., Ltd. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices&id=610&sort=GRN_No&order=DESC&startrow=1&type=basic&search=610

FDA 2022. GRN 1006, Short-chain fructooligosaccharides. Ingredion Incorporated. https://www.fda.gov/media/155444/download

5) *On page 25 of the notice, you state that the literature review was current through October 31, 2021. Please provide additional details about your literature search(es), including the databases and search terms that were used.*

AGG's Response

PubMed was used for the literature search using the terms and search strategy as follows: (resistant dextrin, resistant maltodextrin, soluble corn fiber, Nutriose, Fibersol, PROMITOR, OR FiberSMART) and (human, clinical study, toxicity, or safety), to screen for human clinical studies and toxicity studies.

6) *On page 35 of the notice, you discuss a human clinical study assessing digestive tolerability of the article of commerce, Anderson Global Group's (AGG) resistant dextrin derived from tapioca (Teo and Fairchild, 2021). On page 51 of the notice, in Part 7A References that are Generally Available, it is noted that this manuscript has been submitted for review. Please confirm whether this study has been published, and if so, please provide the updated citation. FDA notes that if this manuscript is not published, this study could only serve as corroborative evidence for a GRAS conclusion, and the citation should be updated in the notice to reflect that it is not generally available.*

AGG's Response

This paper was published in November 2021 in an open access journal, EC Nutrition. An updated citation is as follows:

Teo SYM, Fairchild TJ. Evaluation of the gastrointestinal tolerability of Fibersmart®, a novel dietary fiber, Using a Randomized Controlled Trial in Healthy Men and Women. EC Nutr. 2021; 16.12: 28-36.

7) *AGG's resistant dextrin is derived from tapioca. While tapioca is not considered a major food allergen in the United States, several publications have reported severe allergic reactions. Given that you did not provide any narrative on potential allergenicity of your product, and for completeness of your GRAS evaluation, please provide a short narrative to confirm that allergenicity is not a major safety concern from consumption of your article of commerce.*

AGG's Response

Cassava (tapioca) roots are a staple food in Africa, South America, and Asia as they are mainly eaten as a substitute for potato. However, a few cassava allergy cases have been reported. Case studies on patients with allergic reactions to boiled cassava have been

associated with latex allergies (Antolin-Amerigo et al., 2012; Gaspar et al., 2003, 2012; Galvao et al., 2004; Ibero et al., 2007; Sánchez et al., 2015). As with other allergies, symptoms of a cassava allergy may include hives, swelling, vomiting, or difficulty breathing. Based on the case studies, some of the patients were first diagnosed with an allergy to latex and subsequently to cassava (Gaspar et al., 2003; Ibero et al 2007). Thus, it has been proposed that cassava allergy might be a consequence of primary latex sensitization. Less than 1% of the general population is allergic to latex. However, the prevalence of latex allergy is higher in people who wear latex gloves at work (17%) (de Souza et al., 2008).

Cross-reactivity between different foods occurs due to allergenic proteins showing common IgE epitopes (de Souza et al., 2008). Proteins possibly related to this cross-reactivity can include Hev b 5 protein (Antolin-Amerigo et al., 2012; de Souza 2008; Gaspar et al., 2012), a 42-44 kDa protein similar to Hev b 7 or patatin-like protein (Beezhold et al., 1996; Gaspar et al., 2003) and a homologue to prohevein (Hev b 6) (Blanco, 1999).

The cross-reactivity between cassava and latex could also be attributed to a chitinase, as class I chitinases, plant defense proteins with an N-terminal domain similar to that of prohevein (Hev b 6) in latex, have been particularly implicated in the extensive cross-reactivity in latex allergy. These chitinases have been identified in banana, avocado, and chestnut, and have been considered to be the "panallergens" responsible for latex-fruit syndrome. Approximately 21 and 58% of latex-allergic patients also show allergenic responses to banana, papaya, avocado and kiwi fruits (de Souza et al., 2008; Santos et al., 2011), and the association between latex allergy and allergy to plant-derived foods is called latex-fruit syndrome (Beezhold et al., 1996; Blanco et al., 1999; Santos et al., 2011). In some patient who did not have latex-fruit syndrome, the cross reactivity with latex was related to Hev b 5 (Antolin-Amerigo et al., 2012; Santos et al., 2011, 2013).

There is no indication that tapioca starch or resistant dextrin derived from tapioca starch pose a risk for allergenicity and there are no reports of allergic reaction in the published literature. It is probably due to the fact that the manufacturing process of tapioca starch involves removal of most of the impurities, such as protein, via grinding and centrifugation. Cassava contains 3.37% protein on a dry weight basis, while cassava (tapioca) starch contains only 0.19% protein (https://fdc.nal.usda.gov/fdc-app.html#/food-details/169985/nutrients). Resistant dextrin has less than 0.757% protein or less than the detection limit of the protein assay (it is expected that the protein content of resistant dextrin is less than 0.2% if a more sensitive protein assay method is used because there is no step in enhancing the protein content during the manufacturing of resistant dextrin from tapioca starch). Because tapioca starch and resistant dextrin are carbohydrate ingredients that contain minimum amounts of

protein, the risk of allergenicity attributed to tapioca starch or resistant dextrin is very low.

In addition, the production facility does not process any of the known allergens as follows: wheat, cereals, crustaceans, eggs, fish, peanuts, soy, milk, nuts, mustard, sulphur dioxide and sulphites, sesame seeds, lupin, cocoa, coconut, potentially allergenic fruits, other legumes, latex, or mushrooms.

Taken together, since the production process does not involve any potentially allergenic proteins and the protein content of both the powder and syrup is very low, they present an insignificant risk for potential allergenicity.

References

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We hope we have properly answered FDA questions. If you need further clarifications, please contact me.

Regards,

Susan Cho, Ph.D.
Chief Science Officer
AceOne RS, Inc.
Agent for AGG
6309 Morning Dew Ct.
Clarksville, MD 21029

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Order # Sample ID:	2022-005120-14	**Company:**	Anderson Global Group
Customer Sample ID:	20210513037		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	17.6 %	26-May-2022
	Soluble Dietary Fiber HPLC	67.0 %	26-May-2022
	Soluble Dietary Fiber Total	84.6 %	26-May-2022
	Total Dietary Fiber	84.6 %	26-May-2022
Moisture by Vacuum Oven	Moisture	5.288 %	25-May-2022
[2] pH	pH	4.69	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

Results Approved By: Katrina English
(Authorized Reviewer)

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Order # Sample ID:	2022-005120-13	**Company:**	Anderson Global Group
Customer Sample ID:	20210514027		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	17.7 %	26-May-2022
	Soluble Dietary Fiber HPLC	63.3 %	26-May-2022
	Soluble Dietary Fiber Total	81.0 %	26-May-2022
	Total Dietary Fiber	81.1 %	26-May-2022
Moisture by Vacuum Oven	Moisture	5.386 %	25-May-2022
[2] pH	pH	4.71	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-12	**Company:**	Anderson Global Group
Customer Sample ID:	20210511037		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	22.2 %	26-May-2022
	Soluble Dietary Fiber HPLC	62.8 %	26-May-2022
	Soluble Dietary Fiber Total	85.0 %	26-May-2022
	Total Dietary Fiber	85.1 %	26-May-2022
Moisture by Vacuum Oven	Moisture	5.762 %	25-May-2022
[2] pH	pH	4.60	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-11	**Company:**	Anderson Global Group
Customer Sample ID:	20200402037		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	23.3 %	26-May-2022
	Soluble Dietary Fiber HPLC	60.9 %	26-May-2022
	Soluble Dietary Fiber Total	84.2 %	26-May-2022
	Total Dietary Fiber	84.2 %	26-May-2022
Moisture by Vacuum Oven	Moisture	6.120 %	25-May-2022
[2] pH	pH	4.72	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-09	**Company:**	Anderson Global Group
Customer Sample ID:	20200622037		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	18.4 %	26-May-2022
	Soluble Dietary Fiber HPLC	63.2 %	26-May-2022
	Soluble Dietary Fiber Total	81.6 %	26-May-2022
	Total Dietary Fiber	81.6 %	26-May-2022
Moisture by Vacuum Oven	Moisture	6.119 %	25-May-2022
[2] pH	pH	4.39	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-10	**Company:**	Anderson Global Group
Customer Sample ID:	20191007034		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	20.6 %	26-May-2022
	Soluble Dietary Fiber HPLC	61.9 %	26-May-2022
	Soluble Dietary Fiber Total	82.5 %	26-May-2022
	Total Dietary Fiber	82.5 %	26-May-2022
Moisture by Vacuum Oven	Moisture	6.468 %	25-May-2022
[2] pH	pH	4.22	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-08	**Company:**	Anderson Global Group
Customer Sample ID:	20160905024		
Sample Description:	FiberSMART Tapioca Powder		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.3 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	10.8 %	26-May-2022
	Soluble Dietary Fiber HPLC	69.3 %	26-May-2022
	Soluble Dietary Fiber Total	80.1 %	26-May-2022
	Total Dietary Fiber	80.4 %	26-May-2022
Moisture by Vacuum Oven	Moisture	8.063 %	25-May-2022
[2] pH	pH	4.59	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Order # Sample ID:	2022-005120-04	**Company:**	Anderson Global Group
Customer Sample ID:	20210527033		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	17.6 %	26-May-2022
	Soluble Dietary Fiber HPLC	48.0 %	26-May-2022
	Soluble Dietary Fiber Total	65.6 %	26-May-2022
	Total Dietary Fiber	65.6 %	26-May-2022
Moisture by Vacuum Oven	Moisture	26.320 %	25-May-2022
[2] pH	pH	4.13	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
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Order # Sample ID:	2022-005120-03	**Company:**	Anderson Global Group
Customer Sample ID:	20210504013		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.3 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	16.1 %	26-May-2022
	Soluble Dietary Fiber HPLC	48.2 %	26-May-2022
	Soluble Dietary Fiber Total	64.3 %	26-May-2022
	Total Dietary Fiber	64.6 %	26-May-2022
Moisture by Vacuum Oven	Moisture	26.495 %	25-May-2022
[2] pH	pH	4.10	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
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Order # Sample ID:	2022-005120-02	**Company:**	Anderson Global Group
Customer Sample ID:	20210504023		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.3 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	14.9 %	26-May-2022
	Soluble Dietary Fiber HPLC	53.0 %	26-May-2022
	Soluble Dietary Fiber Total	67.9 %	26-May-2022
	Total Dietary Fiber	68.2 %	26-May-2022
Moisture by Vacuum Oven	Moisture	26.769 %	25-May-2022
[2] pH	pH	4.09	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	10 est. CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
Medallion Labs' services, including this report, are provided subject to all provisions of Medallion' s Standard Terms and Conditions, a copy of which appears at www.medallionlabs.com. Unless otherwise noted above, samples were received in acceptable condition and analyzed as received.

[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-005120-07	**Company:**	Anderson Global Group
Customer Sample ID:	20201011023		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	17.3 %	26-May-2022
	Soluble Dietary Fiber HPLC	47.7 %	26-May-2022
	Soluble Dietary Fiber Total	65.0 %	26-May-2022
	Total Dietary Fiber	65.0 %	26-May-2022
Moisture by Vacuum Oven	Moisture	26.381 %	25-May-2022
[2] pH	pH	3.93	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-005120-01	**Company:**	Anderson Global Group
Customer Sample ID:	20201008033		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	18.0 %	26-May-2022
	Soluble Dietary Fiber HPLC	49.2 %	26-May-2022
	Soluble Dietary Fiber Total	67.2 %	26-May-2022
	Total Dietary Fiber	67.3 %	26-May-2022
Moisture by Vacuum Oven	Moisture	26.330 %	25-May-2022
[2] pH	pH	3.73	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

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[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-005120-06	**Company:**	Anderson Global Group
Customer Sample ID:	20200905023		
Sample Description:	FiberSMART Tapioca Syrup		

Analytical Testing

Method:	Component:	Result:	Test Date:
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.1 %	26-May-2022
	Soluble Dietary Fiber Gravimetric	15.6 %	26-May-2022
	Soluble Dietary Fiber HPLC	48.8 %	26-May-2022
	Soluble Dietary Fiber Total	64.4 %	26-May-2022
	Total Dietary Fiber	64.5 %	26-May-2022
Moisture by Vacuum Oven	Moisture	25.894 %	25-May-2022
[2] pH	pH	3.83	25-May-2022
	Dilution	10 %	25-May-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Coliform using Petrifilm	Coliform count	<10 CFU / g	20-May-2022
Mold using DRBC	Mold	<10 CFU / g	24-May-2022
Yeast using DRBC	Yeast	<10 CFU / g	24-May-2022

Medallion Labs maintains A2LA accreditation to ISO/IEC 17025 for the specific tests listed in certificates # 2769.01 and 2769.02.
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[2] This test is not considered in-scope of our current A2LA accreditation. For a listing of in-scope tests, please visit www.medallionlabs.com.

From: scho@aceoners.com
To: Zhang, Janet
Subject: [EXTERNAL] 회신: GRN001045
Date: Monday, August 15, 2022 9:03:41 AM
Attachments: image001.png
mg_info.txt

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Zhang,

We would like to delete such food codes related to alcoholic light and low-carb beer from the intended use. We apologize for the error.
Thank you. Have a nice day!

Regards,
Susan
Susan Cho, Ph.D.
AceOne RS

보낸 사람: Zhang, Janet <Janet.Zhang@fda.hhs.gov>
보낸 날짜: Wednesday, August 10, 2022 4:07 PM
받는 사람: Susan Cho <scho@aceoners.com>
제목: GRN001045

Good afternoon Dr. Cho,

We note that your dietary exposure assessment in GRN001045 includes food codes for light and low-carb beer. Please clarify whether the intended use of resistant dextrin from tapioca for the category of "beverages, liquid, non-dairy" includes alcoholic light and low-carb beer. If yes, please specify the intended technical effect(s) of the notified substance in this type of alcoholic beverages.

Please kindly provide response within 10 business days. Thank you.

Best regards,
Janet

Jianrong (Janet) Zhang, Ph.D.
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College Park, MD 20740
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