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October 28, 2022

Division of Biotechnology and GRAS Notice Review
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

Subject: GRAS Notification of
Resistant Dextrin from Corn as a Food Ingredient

To whom it may concern,

On behalf of Anderson Global Group (hereinafter referred to as 'AGG'), we are submitting a GRAS notification for Resistant Dextrin from Corn as a food ingredient. The enclosed document provides the notice of a claim that a food ingredient, Resistant Dextrin from Corn, described in the enclosed notification is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS), based on scientific procedures, as a food ingredient. We believe that this determination and notification are in compliance with 21 C.F.R. Part 170, subpart E.

We submit a pdf file for your review. Please feel free to contact me if additional information or clarification is needed as you proceed with the review. We would appreciate your kind attention to this matter.

Sincerely,

Susan Cho, Ph.D.
scho@aceoners.com or sscho397@yahoo.comr
Agent for AGG

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

Prepared for:
Anderson Global Group (AGG)

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

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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 from corn (FiberSMART®-corn) through its agent, AceOne RS, Inc. (formerly NutraSource, Inc.).

1.B. Name and Address of Notifier

Name and Address of Notifier (U.S. Distributor of Resistant Dextrin from Corn)
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

Name and Address of Manufacturer
Company name: Shandong Bailong Chuangyuan Bio-tech Co., Ltd.
Address: National High & New Technology Development Zone, Yucheng City, Shandong Province, China.

1.C. Names of Notified Substance

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

1.D. Intended Conditions of Use

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

The intended use is same as those described in GRN 001045, resistant dextrin-tapioca: (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 the same as those described in GRN 001045: ranging from 1.2 to 10 g per serving. In the case of syrups, the intended use levels are approximately 30% higher than those described for powder because the dietary fiber content of powder and syrup are approximately >80% and 61%, respectively. The intended use levels of syrup will be 30% higher than those described for the powder.

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

	Maximum use level, g/serving		RACC[a], g
Food category	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; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.12).
[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®-corn, 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.

October 14, 2022

Name: Steve Prancevic
Title: Vice President

Date

Please address correspondence to

Susan S. Cho, Ph.D.
AceOne RS, Inc. (formerly NutraSource, Inc.)
5903 Hampton Forest Way, Fairfax, VA 22030
scho@aceoners.com or sscho397@yahoo.com
301-875-6454 (MP)

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

The 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, Other Common Names: resistant dextrin from corn, resistant dextrin-corn, resistant dextrin (corn),
dextrin (fiber), resistant maltodextrin, indigestible dextrin, dietary fiber, corn fiber, soluble corn fiber.
Trade names: FiberSMART®, FiberSMART® from corn, FiberSMART® (corn), or FiberSMART®-corn.

2.A.1.2. Chemical Names

Chemical Abstract Service Name: Dextrin.

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

9004-53-9

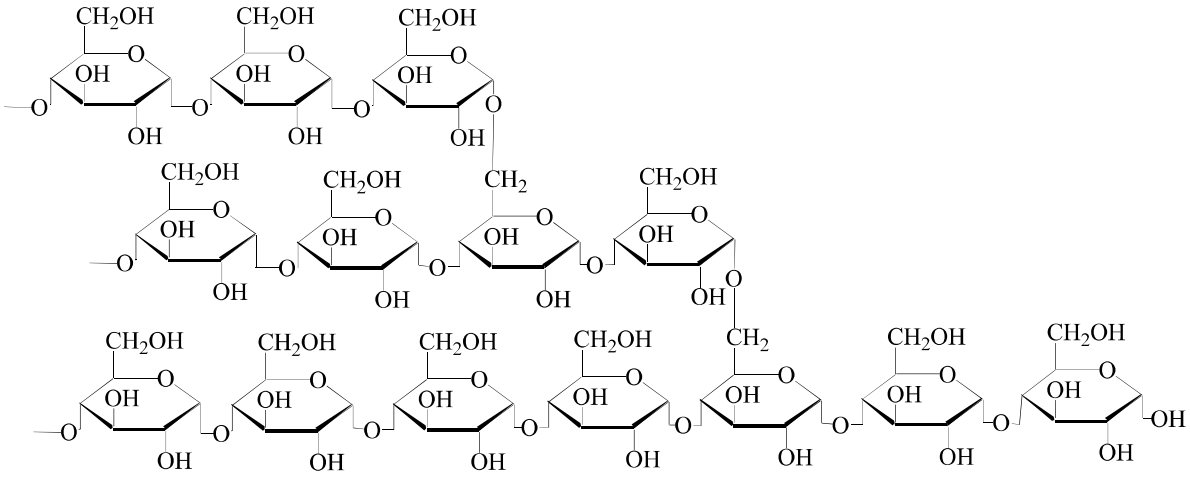
2.A.1.4. Empirical Formula

2.A.1.5. Molecular Weight

The weight average molecular weight (Mw) is 1,508 Daltons.

2.A.1.6. Structural Formula

(a) Starch



(b) Resistant Dextrin

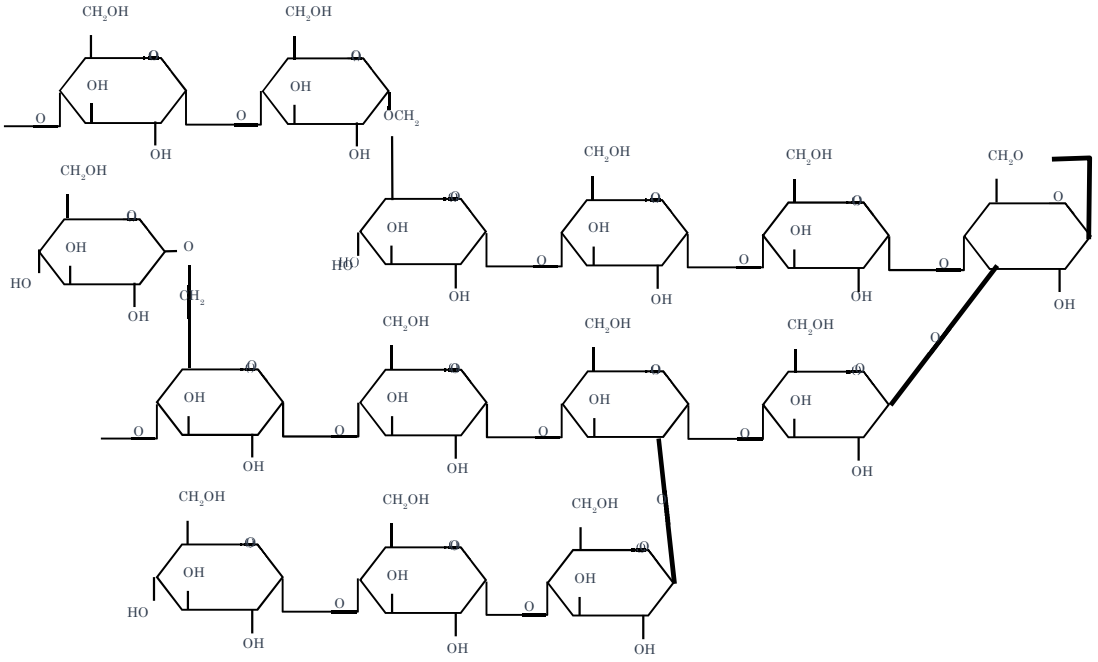


Figure 1. Molecular Structure of Starch (a) and Resistant Dextrin (b)
Resistant dextrin structure, adopted from Hashizume and Okuma (2009)

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. Resistant dextrins can be derived from corn, wheat, or tapioca starch. The subject of this GRAS determination is resistant dextrin (or FiberSMART®) derived from corn starch.

Similarity between Corn- and Wheat-Derived Resistant Dextrins

In June 2018, the FDA acknowledged that 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 65-88%, 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. 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 finished end products have similar properties.

Table 2 compares the total fiber content, DP, and molecular weights of these dietary fibers whose content can be controlled by the degree of purification. As shown in Table 2, the dietary fiber contents are comparable between AGG's resistant dextrin-corn (FiberSMART®-

corn) 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 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-corn, α-1-linkages contribute 65% and β-linkages contribute 35% of total glycosidic linkages. Details are presented in Annex B.

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

Parameters	Starch	NUTRIOSE® 6	NUTRIOSE ® 10	FiberSMART ®-tapioca	FiberSMART®-corn	PDX[1]
Degree of Polymerization	62 x 10^3	12-25	4-10	10.6	9.2	12
M_n	~10^7	2,000-4,000	800-1,500	767	497	800
M_w	~10^7	4,000-6,000	3,500-4,500	1,732	1,508	2,000
Polydispersity (M_n/M_w)	-	1.5-2.5	3-4.5	2.05	3.0	2.5
Total Dietary Fibers, %	0	Average 85	Average, 70	Average, 86	Average, 86.6	90

Expanded from Table 1, GRN 000436 (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.

M_n = the number average molecular weight; Mw= the weight average molecular weight; PDX=polydextrose

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-corn. It is free of pesticides (Annex C) and mycotoxins (Annex D).

2.A.3. Particle Size

Approximately 92-96% (average of 93.9%) of the AGG's resistant dextrin-corn powders passed through U.S. mesh screen size 100 (Annex D). The data indicate that approximately 94% of particles are less than 149 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 corn.

AGG's resistant dextrin-corn is manufactured by Shandong Bailong Chuangyuan Bio-tech Co., Ltd., Dexin Street, National High & New Technology Development Zone, Yucheng City, Shandong Province, China. AGG is an US distributor of resistant dextrin-corn.

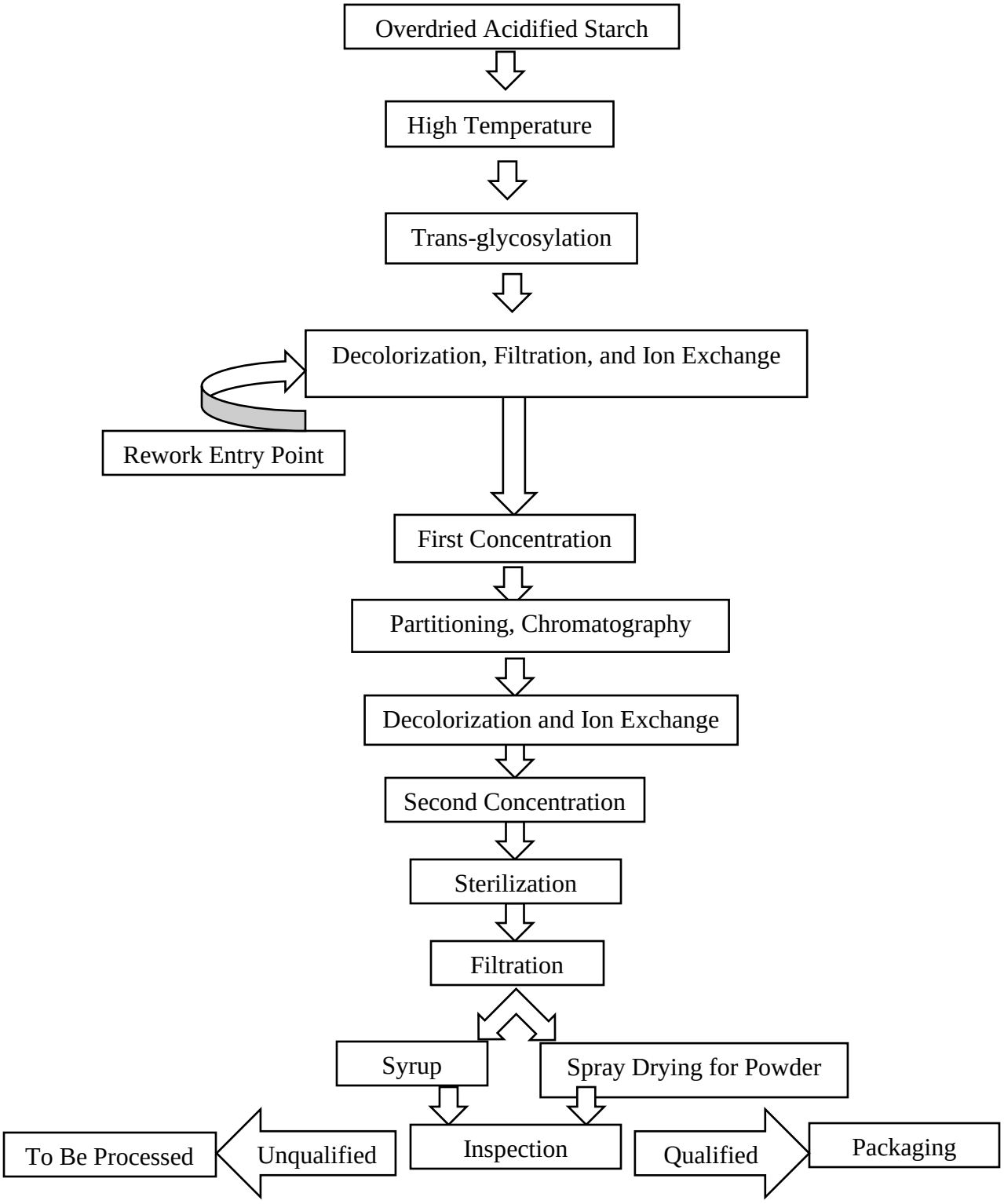
Resistant dextrin is made by a combination of hydrolysis and transglucosidation/ repolymerization processes. Roasting dry starch at acidic conditions results in hydrolysis of the α-1,4 and α-1,6 glycosidic bonds, resulting in shorter starch molecule chain. In the absence of sufficient water, the freed glucose linkages combine within themselves and transglucosidation/ 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>

Shandong Bailong Chuangyuan Bio-tech Co. and rigorously test their final production batches to verify adherence to quality control specifications. Because AGG is ultimately responsible for the quality of resistant dextrin-corn to be distributed in USA, this ingredient is called as AGG's resistant dextrin in this GRAS determination. 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. Shandong Bailong Chuangyuan Bio-tech Co. and AGG routinely evaluate 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 (both corn and tapioca) is similar to that described in GRN 000436 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 000436	GRN 001045	Current notice
Starting material	Corn or wheat starch	Tapioca starch	Corn starch
Acid hydrolysis	Yes	Yes	Yes
Enzyme treatments after converting into pyrodextrin, but before purification	Yes	No	No
Partition chromatography	Yes/No	Yes	Yes
Dietary fiber content with both partition chromatography and ion chromatography	82-88 g/100 g	85-87 g/100 g	84-88 g/100 g
Dietary fiber content with ion chromatography only (no partition chromatography)	65-75 g/100 g	Not applicable	Not applicable

Shandong Bailong Chuangyuan Bio-tech Co. and AGG analyze 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 84 to 88% for the powder form (Table 5-1) and from 67 to 72% for the syrup form (Table 5-2). These values are comparable to other corn- or wheat-derived resistant dextrin reported in GRN 000436 and GRN 001045: ranged from 82 to 88% for powders. 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 61% of total dietary fiber, respectively. The certificates of analysis (COAs) are shown in Annex D. In addition, resistant dextrin-corn powder has the residual protein content of less than 0.1% (Annex E).

Table 4. Specifications for AGG's Resistant Dextrin from Corn

	Powder	Syrup	Method of Analysis
Appearance	White powder		Visual
Total Dietary Fiber, g/100 g	>80	>61	AOAC 2011.25
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	
Hg, mg/kg	<0.2	<0.2	EPA 7473
Aerobic Plate Count, CFU/g	<1,000	<1,000	FDA BAM Ch. 3
Coliform, CFU/g	<10	<10	AOAC 991.14
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 5-1. Analytical Values for AGG's Resistant Dextrin Powder

Parameters	20211101037	20201002034	20201002024
Total Dietary Fiber, g/100 g	88.0	87.5	84.2
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
Coliform, CFU/g	<10	<10	<10
Salmonella, /25 g	Absent	Absent	Absent

Table 5-2. Analytical Values for AGG's Resistant Dextrin Syrup

Parameters	20210801029	20200810013	20200701023
Total Dietary Fiber, g/100 g	71.4	69.3	67.3
Arsenic, µg/kg	<10	<10	<10
Cadmium, µg/kg	<10	<10	<10
Lead, µg/kg	<10	<10	<10
Mercury, µg/kg	<2	<2	<2
Aerobic Plate Count, CFU/g	<10	<10	<10
Molds, CFU/g	<10	<10	<10
Yeasts, CFU/g	<10	<10	<10
Coliform using Petrifilm, CFU/g	<10	<10	<10
Salmonella, /25 g	Absent	Absent	Absent

2.D. Intended Technical Effects

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

2.E. Stability

Resistant dextrin-tapioca powders and syrups are stable for a minimum of 24 and 12 months, respectively. In case of resistant dextrin-tapioca, 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 (GRN 001045 amendment pages 4-6; dated May 27, 2022). In addition, the resistant dextrin-tapioca syrup complies with the described product specifications (>60% total dietary fiber) up to two years in storage. It is expected that resistant dextrin powders and syrups have similar stability, regardless of their sources, as the resistant dextrin in this GRAS determination is similar in specifications compared to another source of resistant dextrin (FiberSMART-tapioca providing >85% dietary fiber) described in the GRN 001045.

AGG's data are consistent with stability data of other dietary fiber ingredients. For example, GRN 000610 (FDA, 2016b) describes shelf stability of isomaltodextrin (IMD) powder, which is composed of approximately 83% dietary fiber. IMD powder is enzymatically produced from starch derived from corn, cassava, etc. IMD is comprised of only α-D-glucose; 7% of α-1 glucosidic linkages (nonreducing end group), 3% of α-1,3, 19% of α-1,4, 49% of α-1,6, 7% of α-1,3,6, and 5% of α-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 IMD can be used as corroborative data when evaluating the storage stability of resistant dextrin. At an ambient condition (25°C and 60% relative humidity), IMD (powder) was stable for 24 months (GRN 000610: pages 33-36).

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

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 (powder)/serving (corresponding to 1.56-13.0 g/serving for syrup): (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 EDI of resistant dextrin was 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 and each of the selected subpopulations 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 the 90th percentile per user is 26.5 g/day. The per user 90th percentile for the various age and gender subgroups ranged from 20.2 g/day (children 1 to 6 years) to 39.3 g/day (males 19+ years) (Table 6).

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 the 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 intake level (UL) for dietary fiber.

Table 6. 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 2day survey dataset from the 2017-2018 NHANES; 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. 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).

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 the 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

Not 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 (powder; corresponding to 1.56-13.0 g/serving for syrup): (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 90^{th} percentile intake was 26.5 g/day in all-users. AGG's resistant dextrin-corn will currently market resistant dextrin ingredients; thus, the cumulative exposure is not expected to change. FDA has established a DRV for dietary 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 000436, FDA, 2013; GRN 001045, FDA, 2022) as well as other "resistant" polyglucose ingredients, such as polydextrose (21 CFR §172.841) and isomaltodextrin (GRN 000610; 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."

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. Thus, 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 'no question' letters on GRAR notices related to food uses of resistant dextrins including GRN 000436 (enzyme-modified dextrins or resistant dextrins, NUTRIOSE FM, derived from corn; NUTRIOSE FB, wheat-based; Roquette) and GRN 001045 (resistant dextrin-tapioca; FiberSMART-tapioca). As the resistant dextrin in this GRAS determination is similar in specifications compared to other sources of resistant dextrins described in the previous FDA GRAS notices such as GRNs 000436 and 001045 (NUTRIOSE 6 providing an average of 85% dietary fiber; NUTRIOSE 10 providing an average of 70% of dietary fiber; FiberSMART-tapioca providing >85% dietary fiber), it is recognized that the information and data in GRN 000436 and GRN 001045 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 000436 and GRN 001045. This notice incorporates by reference the safety and metabolism studies discussed in GRN 000436 (pages 18-26) and GRN 001045 (pages 25-43) and will not discuss previously reviewed references in detail. In addition, mutagenicity and acute toxicity of AGG's resistant dextrin-corn are reviewed in this notice. The subject of the present GRAS assessment is resistant dextrin derived from corn or FiberSMART®-corn. Our review covers the literature published up to August 31, 2022.

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 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 for the caloric value of soluble dietary fibers 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

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

In the study by Case et al. (2021), AGG's FiberSMART® preparation (derived from corn starch) was tested for mutagenicity using *Salmonella typhimurium* TA97, TA98, TA100, TA102, or TA1535 with or without S9 activation (Table 7). 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.

Studies Reviewed in Previous GRAS Notices

AGG's resistant dextrin-tapioca or FiberSMART®-tapioca was not mutagenic at concentrations up to 5,000 μg/plate in *Salmonella typhimurium* TA97, TA98, TA100, TA102, or TA1535 with or without S9 activation (Case et al., 2021).

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 7. Bacterial Mutation Assay Results for AGG's Resistant Dextrin-Corn

	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
	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
	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 8 summarized the animal toxicity studies conducted on AGG's resistant dextrin-corn (FiberSMART®-corn) and other sources of resistant dextrins.

Table 8. 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®-corn or corn)	30 SD rats	0 or 20 g/kg bw, FiberSMART® (source, corn)	Single dose, 14 d observation	LD_{50}> 20.0 g/kg bw	Case et al, 2021
		20 g/kg bw, FiberSMART® (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, 4,360mg/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)	

NOAEL=No Observed Adverse Effect Levels; 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 from Corn (Table 10)

The acute oral toxicity of AGG' resistant dextrins, FiberSMART® (tapioca starch and corn starch-based), were 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 the 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) were well above 20 g/kg bw, the highest dose tested. The data indicate that both types of resistant dextrins are 'relatively harmless' (Altug, 2003).

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

As shown in Table 8, a subchronic study reported that No-Observed-Adverse-Effect Levels (NOAEL) 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 of AGG's Resistant Dextrin Derived from Tapioca

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. 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. 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 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).

Subchronic Toxicity Study of Resistant Dextrin Derived from Wheat Starch

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, the highest levels tested in males and females, respectively (Table 8).

Conclusions from Animal Toxicity Studies

AGG's resistant dextrin, derived from corn, showed an LD_{50} value higher than 20 g/kg bw. Regardless of sources, resistant dextrins showed similar toxicity profiles; >4,360 mg/kg bw/day in males and a minimum of 5,000 mg/kg bw/day for females. Due to structural similarity and specifications, it is reasonable to expect that a toxicity profile of AGG's resistant dextrin-corn is similar to those of other sources of resistant dextrin.

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 GRAS determination (Table 9).

Studies Discussed in Previous GRAS Notices

As discussed in Part 2, 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.'

Resistant Dextrin-Corn

Baer et al (2014) also reported that consumption of resistant maltodextrin (resistant dextrin marketed by Matsutani Chemical Industry; brand name, Fibersol-2, probably derived from corn or tapioca starch) 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 (aged 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 (aged 18-60 years).

Other Sources of Resistant Dextrins

In a randomized, crossover clinical study by Teo and Fairchild (2021), 40 participants (aged 18-75 years; Australia) were randomized to receive 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 dose. 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).

In a study by Pasman et al. (2006), 48 volunteers received resistant dextrin-wheat (NUTRIOSE FB 06) at daily dose of 0 (maltodextrin-placebo), 30, or 45 g for 4 weeks. 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 control, 30 g, and 45 g groups, respectively).

Vermorel et al. (2004) demonstrated that ingestion of 100 g of resistant dextrin (NUTRIOSE FB 06 derived from wheat starch) did not cause severe digestive disorders due to a progressive adaptation and distribution in 6 equal doses per day. However, excessive flatulence and slight abdominal pain were recorded in some subjects after intakes above 50 g/day of resistant dextrin.

Table 9. Human Digestive Tolerance Studies with Large Amounts of Resistant Dextrins

Reference	Subjects	Daily Dose of RD	Source	Control	Duration; Design	Measurements	Safety-related Outcomes
Baer et al, 2014	15 males (35-55 y)	0, 25, or 50 g RMD from (Matsutani Chemicals)	Probably corn	Malto-dextrin	24 d with >2 wk washout; X	Bowel movement; stool weight; excretion of energy and nitrogen; gut microbiota	No adverse effects on measured outcomes
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	Escalating doses-1 wk for each dose with 3 wk washout; X	Gastrointestinal tolerance; changes in body anthropometrics; and vital signs	No adverse effects on measured outcomes
Pasman et al., 2006	48 men (20-45 y; BMI <31 kg/m^2)	0, 30, or 45 g Nutriose FB	Wheat	Malto-dextrin	5 wk (1^{st} week, half dose; 4 wk, full dose); P	Gastrointestinal tolerance; gut microflora; fermentation by breath hydrogen excretion measurement; hunger and satiety scores and food preferences	No adverse effects on measured outcomes
Vermorel et al., 2004	10 healthy males (mean age, ~23 y)	0, increasing doses from 20 to 100 g Nutriose FB	Wheat	Dextrose	31 d with 4 wk washout period; X	Gastrointestinal tolerance; metabolisable energy; mineral absorption	RD was well tolerated at <50 g/day; higher doses (>50 g/day) may result in flatulence and slight abdominal pain with no diarrhea

RD=resistant dextrin; RMD=resistant maltodextrin, synonymous with the term, 'resistant dextrin'; P=parallel design; X=crossover design.

6.B.4.2. Human Clinical Studies Testing Other Parameters

Previous GRAS notices (GRNs 000436 and 001045) extensively discussed the safety of resistant dextrins found from various human clinical studies. Thus, this review briefly summarizes the discussion presented in GRNs 000436 and 0001045.

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 (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 Fibersol-2 may be derived from either corn or tapioca starch.

Other human studies evaluated the effects of resistant dextrins on the parameters listed below. Due to an abundance of literature, we have limited our review to studies with an intervention duration of 3 weeks or longer and daily doses of 20 g or higher unless digestive tolerance was tested. In addition, crossover studies employing no washout period are not included in this review.

(a) Adverse events and /or compliance (Guerin-Deremaux et al., 2011a; Jakeman et al., 2016),
(b) Gut microbiota and/or fecal characteristics (Burns et al., 2018; Mai et al., 2022; Nishimoto et al., 2022; Ukhanova et al., 2012),
(c) Gastrointestinal functions (Whisner et al., 2016),
(d) Glucose metabolism and/or metabolic indicators (Gholizadeh Shamasbi et al., 2019; Hashizume et al., 2012; Nishimoto et al., 2022; Nomura et al., 1992),
(e) Satiety/energy intake (Guerin-Deremaux et al., 2011a, 2011b; Hashizume et al., 2012),
(f) Bone health indicators (Jakeman et al., 2016; Whisner et al., 2016),
(g) Mineral absorption (Whisner et al., 2016), and
(h) Liver function indicators (Nomura et al., 1992)

All of these studies listed above reported no adverse effects of resistant dextrins up to 60 g/day on the measured outcomes.

Summary of Human Clinical Studies

Although resistant dextrin intake at a daily dose of 60 g for 12 weeks did not result 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 -50 g were well tolerated with no major side effects in humans, regardless of their sources.

Table 10. Human Clinical Studies Reporting No adverse Effects of Resistant Dextrins

Reference	Subjects	Daily Dose of RD	Source	Control	Duration	Measurements
Studies Using Resistant Dextrin Derived from Corn Starch						
Mai et al., 2022	49 subjects (18-50 y)	0, 15, or 25 g RD	Corn	Not specified	3 wk with 2 wk washout	Gut microflora
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
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	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
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	No control	12 wk	Serum lipid and plasma glucose concentrations, erythrocytes 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)	corn or tapioca)	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
Burns et al., 2018	51 healthy adults (mean age, 26.3 y)	0, 15 or 25 g RD (Fibersol-2)		Maltodextrin in beverage	3 wk with 2 wk washout	Stool weights; fecal bifidobaterial counts; total dietary fiber intakes
Nishimoto et al., 2022	29 Japanese subjects whose hemoglobin A1c (HbA1c) levels are larger than 6% (age, NA)	0 or 20 g RD (Fibersol-2)		6 g Maltodextrin	24 wk	Intestinal microbiome and metabolome profiles; clinical chemistry related to glucose metabolism
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		3 wk		Satiety and hunger feelings

d=days; 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; mo=months; RBC=red blood cells; RD=resistant dextrin; TNF-α=tumor necrosis factor alpha; wk=weeks.

*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. Potential Adverse Effects

The IOM (2005) has not established an UL for dietary fiber in regards to 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 years 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 corn) 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-corn 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 (powder) 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 intended use levels of syrup will be 30% higher than those described for the powder.

4. The U.S. per capita mean intake from all the selected food categories is 14.4 g/day and the corresponding 90th percentile intake is 26.5 g/day. FDA has established a DRV for dietary fiber as 28 g/day. It is not expected 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-corn, was determined to be higher than 20 g/kg bw in rats, indicating that the substance belongs to the group that has the lowest toxicity rating. Bacterial reverse mutation assay showed that AGG's resistant dextrin-corn 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-tapioca was 5,000 mg/kg bw/day in both male and female rats. The NOAEL values for resistant dextrin derived from wheat were 4,360 mg/kg bw/day and 6,500 mg/kg bw/day in male and female rats, respectively. Due to similarity in specifications and composition of resistant dextrin-corn compared to other sources of resistant dextrins, the NOAELs found for wheat- and tapioca-based resistant dextrins are pertinent when evaluating the safety of the resistant dextrin-corn in this GRAS determination.

7. In human studies, various resistant dextrin preparations were well tolerated at daily doses up to 50 g.

8. In previous GRAS notices (GRNs 000436 and 001045) to the FDA, the safety of resistant dextrins was 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, resistant dextrin-corn or FiberSMART®-corn, as a food ingredient in the U.S. for use in selected conventional foods.

Two other sources of resistant dextrin (derived from tapioca and wheat) have been evaluated by the FDA in the past few years for proposed incorporation of resistant dextrin ingredients in foods. Relevant U.S. GRAS notifications include GRN 000436 (FDA, 2013) and GRN 001045 (FDA, 2022). These GRAS notices 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 these notifications, there were no significant adverse effects/events or tolerance issues attributable to resistant dextrins. 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 FDA 'no question' letters.

The AGG's resistant dextrin derived from corn starch, that is the subject of this GRAS determination, contains over 80% and 61% 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-corn include bacterial reverse mutation study and acute toxicity in rats. In these reports, no evidence of toxicity was noted. The publicly available scientific literature on the consumption and the safety of resistant dextrins 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 concludes that the intended use of its resistant dextrin-corn 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

AGG is 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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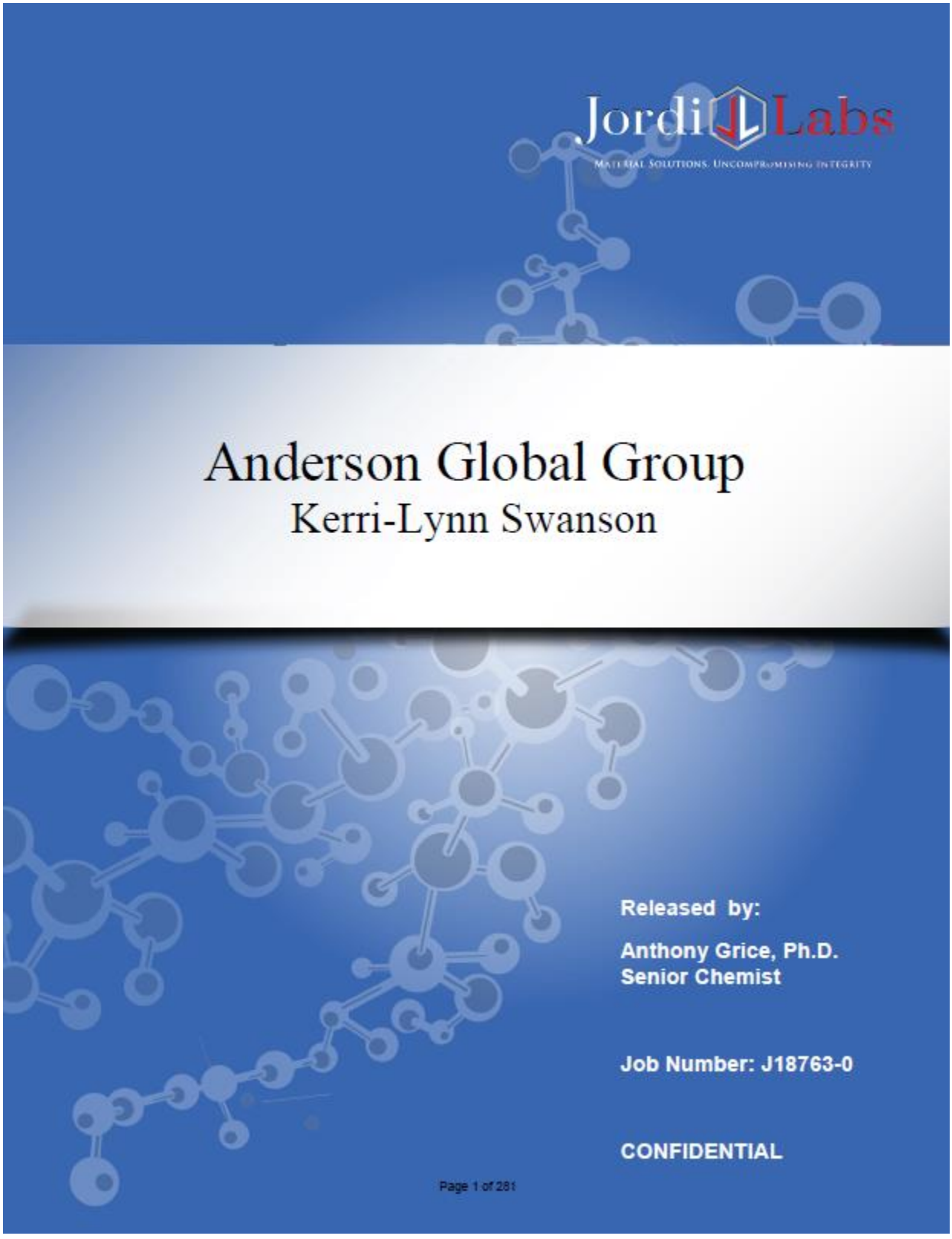
7.B. References That Are Not Generally Available

Not applicable.

Annex A. Molecular Weight Distribution of FiberSMART® -Corn



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June 6, 2022

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 CP90, Resistant Dextrin Powder Lot# 20211006037*
   (Referred to as *Lot# 20211006037*)
2. *FiberSMART CP90, Resistant Dextrin Powder, Lot # 20210412027*
   (Referred to as *Lot# 20210412027*)
3. *FiberSMART CP90, Resistant Dextrin Powder, Lot # 20211101037*
   (Referred to as *Lot# 20211101037*)

The following test was performed:

1. Standardized Gel Permeation Chromatography (GPC)

Objective

Three (3) samples were submitted for analysis, similar to **J18185-0** using the conditions depicted in **Figure 1**. It was explained that the samples were derived from starch which have 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 J18185, 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 J18185, 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. J18185 conditions which were replicated in this report

Summary of Results

Samples exhibit similar molecular weight distributions, all with M_w values of approximately 1.4 – 1.6 kDa relative to polysaccharide standards. 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 DP40, and calculated values have been reported up DP42 (**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.

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

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

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

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, tetra-detection 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

The samples exhibited M_w values ranging between approximately 1.4 – 1.6 kDa relative to polysaccharide standards. Samples were integrated until the retention time of the lowest standard (180 Da, see **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 DP40, and calculated values have been reported up DP42 (**Table 2**). Cumulative weight plots were used in the calculations, and are presented separately in the data section of this report. The equation for average DP of the samples was determined by accounting for the loss of water (18.02 Da) from the terminal glucose for the remaining polymer to be divisible by the repeating monomer unit (162.14 Da). This equation can be verified by using the known molecular weight and DP of any of the glucose polymers presented in **Table 2**.

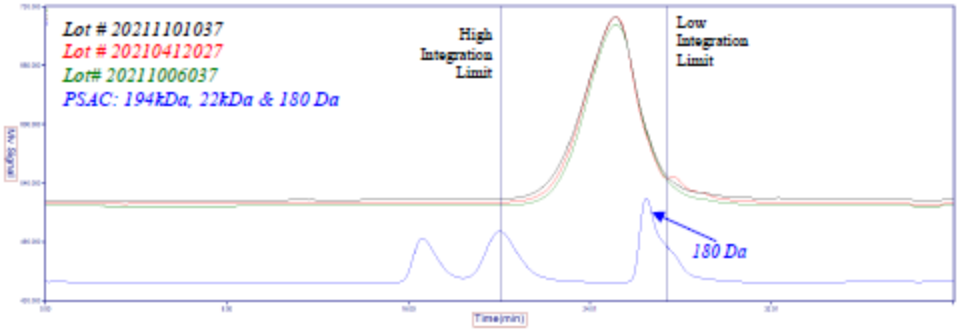


Figure 2. Overlay of the refractive index chromatograms of the samples with standards.

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# 20211006037	1	470	486	1,411	1,439	3,102	3,090	3.00	2.96	8.76
	2	494		1,443		3,035		2.92		
Lot # 20210412027	1	508	503	1,502	1,513	3,252	3,384	2.96	3.01	9.22
	2	502		1,541		3,592		3.07		
Lot # 20211101037	1	509	501	1,579	1,572	3,545	3,580	3.10	3.14	9.58
	2	504		1,571		3,561		3.12		

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

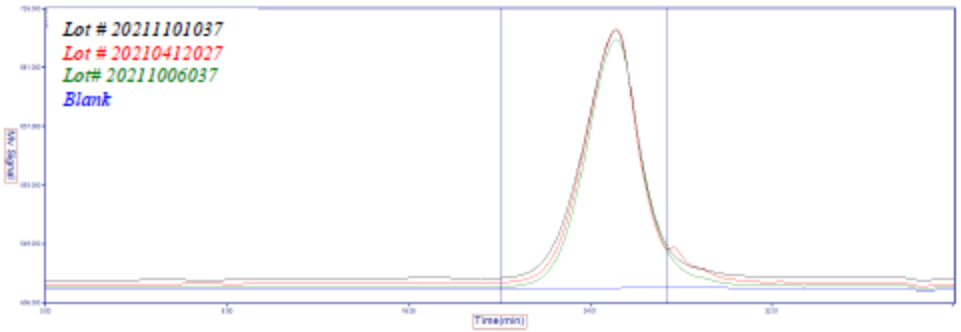


Figure 3. Overlay of refractive index (RI) chromatograms of the samples and blank

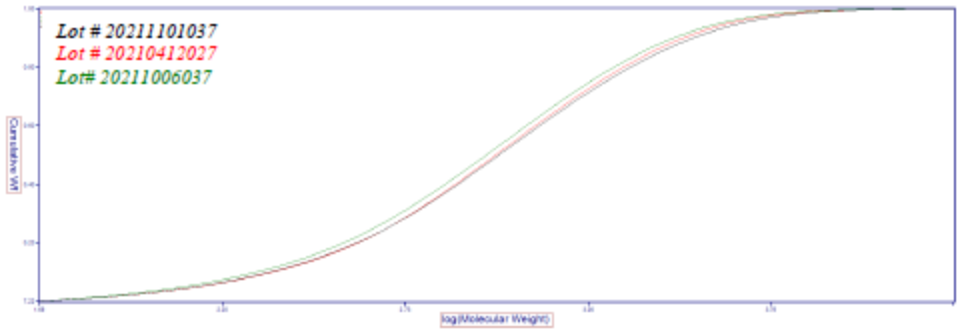


Figure 4. Overlay of cumulative weight fraction curves for the samples

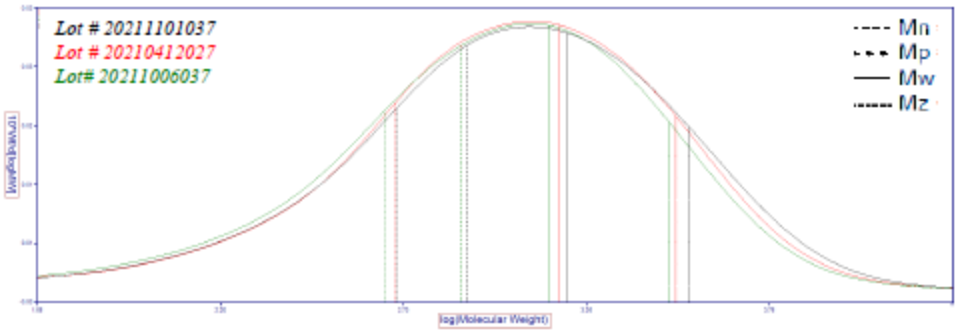


Figure 5. Overlay of molecular weight distribution curves for the samples

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

Degree of Polymerization	Run	Mw (g/mol)	*Lot: 20210412027*				*Lot: 20211006037*				*Lot: 20211101037*			
			Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg
DP1 *Glucose*	1	181	7.64	7.75	7.64	7.75	8.78	8.43	8.78	8.43	7.77	7.84	7.77	7.84
	2		7.86		7.86		8.07		8.07		7.90		7.90	
DP2 *Maltose*	1	343	17.13	17.30	9.49	9.55	19.18	18.53	10.40	10.11	17.32	17.46	9.55	9.63
	2		17.47		9.61		17.88		9.81		17.60		9.70	
DP3 *Maltotriose*	1	505	26.81	27.00	9.68	9.70	29.31	28.45	10.13	9.92	26.76	26.96	9.44	9.50
	2		27.19		9.72		27.59		9.71		27.15		9.55	
DP4	1	667	35.91	36.09	9.10	9.09	38.42	37.50	9.11	9.05	35.52	35.73	8.76	8.78
	2		36.26		9.07		36.57		8.98		35.94		8.79	
DP5	1	829	43.84	43.98	7.93	7.90	46.25	45.34	7.83	7.84	43.21	43.42	7.69	7.69
	2		44.12		7.86		44.42		7.85		43.63		7.69	
DP6	1	991	50.59	50.69	6.75	6.71	52.91	52.04	6.66	6.71	49.80	50.00	6.59	6.58
	2		50.78		6.66		51.17		6.75		50.20		6.57	
DP7	1	1153	56.34	56.40	5.75	5.72	58.61	57.80	5.70	5.76	55.44	55.63	5.64	5.63
	2		56.46		5.68		56.99		5.82		55.81		5.61	
DP8	1	1316	61.30	61.33	4.96	4.93	63.54	62.79	4.93	4.99	60.31	60.48	4.87	4.86
	2		61.36		4.90		62.04		5.05		60.65		4.84	
DP9	1	1478	65.57	65.57	4.27	4.24	67.76	67.08	4.22	4.29	64.49	64.65	4.18	4.17
	2		65.56		4.20		66.40		4.36		64.80		4.15	
DP10	1	1640	69.28	69.25	3.71	3.68	71.42	70.81	3.66	3.72	68.12	68.27	3.63	3.62
	2		69.21		3.65		70.19		3.79		68.41		3.61	
DP11	1	1802	72.52	72.46	3.24	3.22	74.61	74.05	3.19	3.25	71.30	71.43	3.18	3.17
	2		72.40		3.19		73.49		3.30		71.56		3.15	
DP12	1	1964	75.37	75.29	2.85	2.83	77.39	76.89	2.78	2.84	74.09	74.21	2.79	2.78
	2		75.20		2.80		76.39		2.90		74.33		2.77	
DP13	1	2126	77.88	77.78	2.51	2.49	79.82	79.38	2.43	2.49	76.56	76.67	2.47	2.46
	2		77.67		2.47		78.93		2.54		76.78		2.45	
DP14	1	2288	80.10	79.98	2.22	2.21	81.96	81.57	2.14	2.19	78.75	78.85	2.19	2.18
	2		79.86		2.19		81.17		2.24		78.95		2.17	
DP15	1	2451	82.09	81.95	1.99	1.97	83.85	83.50	1.89	1.94	80.72	80.81	1.97	1.96
	2		81.81		1.95		83.15		1.98		80.89		1.94	
DP16	1	2613	83.84	83.69	1.75	1.74	85.51	85.21	1.66	1.71	82.46	82.54	1.74	1.74
	2		83.54		1.73		84.90		1.75		82.62		1.73	

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

Degree of Polymerization	Run	Mw (g/mol)	*Lot: 20210412027*				*Lot: 20211006037*				*Lot: 20211101037*			
			Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg
DP17	1	2775	85.40	85.24	1.56	1.54	86.98	86.71	1.47	1.51	84.02	84.10	1.56	1.56
	2		85.07		1.53		86.44		1.54		84.17		1.55	
DP18	1	2937	86.80	86.63	1.40	1.39	88.28	88.05	1.30	1.34	85.42	85.49	1.40	1.39
	2		86.45		1.38		87.81		1.37		85.55		1.38	
DP19	1	3099	88.04	87.86	1.24	1.23	89.43	89.23	1.15	1.18	86.68	86.74	1.26	1.26
	2		87.67		1.22		89.02		1.21		86.80		1.25	
DP20	1	3261	89.16	88.97	1.12	1.11	90.46	90.29	1.03	1.06	87.82	87.88	1.14	1.14
	2		88.77		1.10		90.11		1.09		87.93		1.13	
DP21	1	3423	90.16	89.96	1.00	1.00	91.38	91.23	0.92	0.94	88.84	88.89	1.02	1.02
	2		89.76		0.99		91.07		0.96		88.94		1.01	
DP22	1	3586	91.07	90.86	0.91	0.90	92.20	92.07	0.82	0.85	89.78	89.83	0.94	0.94
	2		90.65		0.89		91.94		0.87		89.87		0.93	
DP23	1	3748	91.88	91.67	0.81	0.81	92.93	92.82	0.73	0.75	90.62	90.66	0.84	0.84
	2		91.45		0.80		92.71		0.77		90.70		0.83	
DP24	1	3910	92.60	92.39	0.72	0.72	93.58	93.49	0.65	0.67	91.38	91.42	0.76	0.76
	2		92.17		0.72		93.40		0.69		91.46		0.76	
DP25	1	4072	93.26	93.04	0.66	0.66	94.17	94.10	0.59	0.60	92.08	92.12	0.70	0.70
	2		92.82		0.65		94.02		0.62		92.15		0.69	
DP26	1	4234	93.85	93.63	0.59	0.59	94.70	94.64	0.53	0.55	92.71	92.74	0.63	0.63
	2		93.40		0.58		94.58		0.56		92.77		0.62	
DP27	1	4396	94.38	94.16	0.53	0.53	95.17	95.13	0.47	0.48	93.28	93.31	0.57	0.57
	2		93.93		0.53		95.08		0.50		93.34		0.57	
DP28	1	4558	94.86	94.64	0.48	0.48	95.60	95.57	0.43	0.44	93.81	93.84	0.53	0.53
	2		94.41		0.48		95.53		0.45		93.86		0.52	
DP29	1	4721	95.30	95.08	0.44	0.44	95.98	95.96	0.38	0.39	94.29	94.32	0.48	0.48
	2		94.85		0.44		95.93		0.40		94.34		0.48	
DP30	1	4883	95.69	95.47	0.39	0.39	96.33	96.32	0.35	0.36	94.73	94.75	0.44	0.44
	2		95.24		0.39		96.30		0.37		94.77		0.43	
DP31	1	5045	96.05	95.83	0.36	0.36	96.64	96.63	0.31	0.32	95.13	95.15	0.40	0.40
	2		95.60		0.36		96.62		0.32		95.17		0.40	
DP32	1	5207	96.37	96.15	0.32	0.32	96.92	96.92	0.28	0.29	95.50	95.52	0.37	0.37
	2		95.92		0.32		96.92		0.30		95.53		0.36	
DP33	1	5369	96.67	96.45	0.30	0.30	97.18	97.19	0.26	0.27	95.83	95.85	0.33	0.33

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

Degree of Polymerization	Run	Mw (g/mol)	*Lot: 20210412027*				*Lot: 20211006037*				*Lot: 20211101037*			
			Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg	Cumulative Wt %	Avg	% Solids for DP	Avg
	2		96.22		0.30		97.19		0.27		95.86		0.33	
DP34	1	5531	96.93	96.71	0.26	0.27	97.41	97.42	0.23	0.23	96.14	96.16	0.31	0.31
	2		96.49		0.27		97.43		0.24		96.17		0.31	
DP35	1	5693	97.18	96.96	0.25	0.25	97.62	97.64	0.21	0.22	96.43	96.44	0.29	0.29
	2		96.73		0.24		97.65		0.22		96.45		0.28	
DP36	1	5856	97.40	97.18	0.22	0.22	97.81	97.83	0.19	0.19	96.69	96.70	0.26	0.26
	2		96.96		0.23		97.85		0.20		96.71		0.26	
DP37	1	6018	97.60	97.39	0.20	0.20	97.99	98.01	0.18	0.18	96.93	96.94	0.24	0.24
	2		97.17		0.21		98.03		0.18		96.94		0.23	
DP38	1	6180	97.79	97.58	0.19	0.19	98.15	98.18	0.16	0.17	97.15	97.16	0.22	0.22
	2		97.36		0.19		98.20		0.17		97.16		0.22	
DP39	1	6342	97.96	97.75	0.17	0.17	98.29	98.32	0.14	0.14	97.35	97.36	0.20	0.20
	2		97.53		0.17		98.35		0.15		97.36		0.20	
DP40	1	6504	98.11	97.90	0.15	0.16	98.42	98.45	0.13	0.13	97.54	97.54	0.19	0.19
	2		97.69		0.16		98.48		0.13		97.54		0.18	
DP41	1	6666	98.25	98.05	0.14	0.15	98.54	98.58	0.12	0.13	97.71	97.71	0.17	0.17
	2		97.84		0.15		98.61		0.13		97.71		0.17	
DP42	1	6828	98.38	98.18	0.13	0.13	98.65	98.69	0.11	0.11	97.87	97.87	0.16	0.16
	2		97.97		0.13		98.72		0.11		97.87		0.16	

$$\%\ Solids\ for\ DP\ = Cumulative\ Wt\ \%\ at\ DP_n - Cumulative\ Wt\ \%\ at\ DP_{n-1}$$

Analysis Conditions

GPC

Samples were monitored using an Agilent 1260 refractive index detector. Data acquisition and handling was made with Jordi GPC software.

Data was obtained under the following conditions:

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, 334k, 194k, 107k, 47.1k, 22k, 6.3k, 667 and 180 Da

Closing Comments

Jordi Labs' reports are issued solely for the use of the clients to whom they are addressed. No quotations from reports or use of the Jordi name is permitted except as authorized in writing. The liability of Jordi Labs with respect to the services rendered shall be limited to the amount of consideration paid for such services and do not include any consequential damages.

Jordi Labs specializes in polymer testing and has 30 years' experience doing complete polymer deformulations. We are one of the few labs in the country specialized in this type of testing. We will work closely with you to help explain your test results and solve your problem. We appreciate your business and are looking forward to speaking with you concerning these results.

Sincerely,

Joel Worthington

Joel Worthington, B.Sc.
Chemist
Jordi Labs LLC

Anthony Grice

Anthony Grice, Ph.D.
Investigative Group Leader
Jordi Labs LLC

Pages 12-281, GPL raw data are available upon request.

Annex B. Glycosidic Linkage Characterization of FiberSMART®-Corn

Final Report

TO :	Steve Prancevic, Anderson Advanced Ingredients
CC :	
FROM :	Anton Terekhov
DATE :	May 31, 2022
SUBJECT :	Linkage and anomeric configuration analysis

1

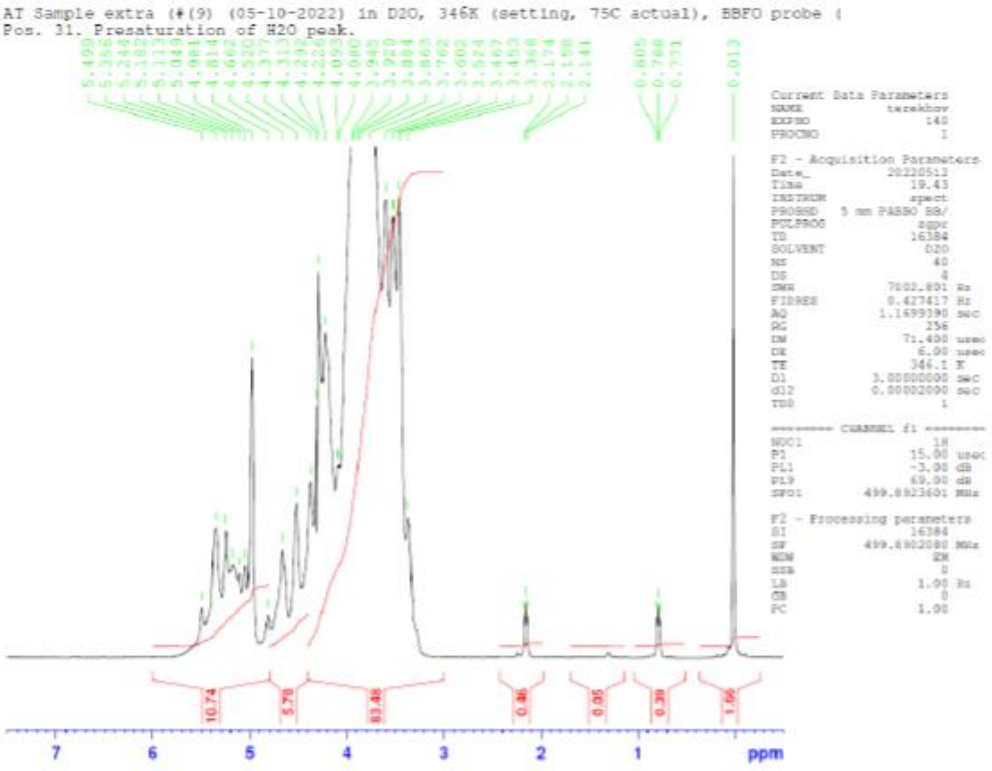
Results:

Table 1. Linkages

Linkages	% Linkage
T-Glc	37.4±2.7
1,3-Glc	7.4±0.7
1,2-Glc	6.0±0.3
1,6-Glc	23.7±1.4
1,4-Glc	11.9±0.2
1,3,4-Glc	1.6±0.1
1,2,3-Glc	0.5±0.0
1,2,4-Glc	1.2±0.2
1,3,6-Glc	3.0±0.4
1,4,6-Glc	4.5±0.6
1,2,6-Glc	2.9±0.6

WHISTLER CENTER for Carbohydrate Research — PURDUE UNIVERSITY

Chromatogram 1. NMR



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

Table 2. NMR – anomeric configuration

% α-Glc	% β-Glc
65.0	35.0

3

Annex C. Certificate of Analysis (COAs) for Pesticides

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Eurofins Microbiology Laboratories (Los Angeles)

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ANDERSON GLOBAL GROUP, LLC

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

ANALYTICAL REPORT

AR-22-QR-019913-01

Client Code: QR0000052

Received On: 10Jun2022
Reported On: 22Jun2022

Eurofins Sample Code:	111-2022-06100156	**Sample Registration Date:**	10Jun2022
Client Sample Code:	20211101037	**Condition Upon Receipt:**	acceptable, 21.2°C
Sample Description:	FiberSMART CP90	**Sample Reference:**	Resistant Dextrin

QA01P - Pesticides Quechers GC-MSMS	**Reference**	**Accreditation**	**Completed**	**Sub**
	AOAC 2007.01		22Jun2022	1

Parameter	**Result**
Screened pesticides	Not Detected at LOQ

QA01R - Pesticides Quechers-LC-MS/MS	**Reference**	**Accreditation**	**Completed**	**Sub**
	AOAC 2007.01		22Jun2022	1

Parameter	**Result**
Screened pesticides	Not Detected at LOQ

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, Louisiana

Respectfully Submitted,

Viridiana Castro
Assistant Laboratory Manager

eurofins | Eurofins Microbiology Laboratories (Los Angeles)

Eurofins Microbiology Laboratories (Los Angeles)

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ANDERSON GLOBAL GROUP, LLC

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

Client Code: QR0000052

ANALYTICAL REPORT

AR-22-QR-019915-01

Received On: 10Jun2022
Reported On: 22Jun2022

Eurofins Sample Code:	111-2022-06100158	**Sample Registration Date:**	10Jun2022
Client Sample Code:	20201002034	**Condition Upon Receipt:**	acceptable, 21.2°C
Sample Description:	FiberSMART CP90	**Sample Reference:**	Resistant Dextrin

QA01P - Pesticides Quechers GC-MSMS	**Reference**	**Accreditation**	**Completed**	**Sub**
	AOAC 2007.01		22Jun2022	1

Parameter	**Result**
Screened pesticides	Not Detected at LOQ

QA01R - Pesticides Quechers-LC-MS/MS	**Reference**	**Accreditation**	**Completed**	**Sub**
	AOAC 2007.01		22Jun2022	1

Parameter	**Result**
Screened pesticides	Not Detected at LOQ

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, Louisiana

Respectfully Submitted,

[redacted]

Viridiana Castro
Assistant Laboratory Manager

6/22/22 3:22 pm

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ANALYTICAL REPORT

AR-22-QR-019914-01

Client Code: QR0000052

Received On: 10Jun2022
Reported On: 22Jun2022

Eurofins Sample Code:	111-2022-06100157	**Sample Registration Date:**	10Jun2022
Client Sample Code:	20201202024	**Condition Upon Receipt:**	acceptable, 21.2°C
Sample Description:	FiberSMART CP90	**Sample Reference:**	Resistant Dextrin

QA01P - Pesticides Quechers GC-MSMS	Reference	Accreditation	Completed	Sub
	AOAC 2007.01		22Jun2022	1

Parameter	Result
Screened pesticides	Not Detected at LOQ

QA01R - Pesticides Quechers-LC-MS/MS	Reference	Accreditation	Completed	Sub
	AOAC 2007.01		22Jun2022	1

Parameter	Result
Screened pesticides	Not Detected at LOQ

Subcontracting partners:
1 - Eurofins Central Analytical Laboratories, Louisiana

Respectfully Submitted,

Viridiana Castro
Assistant Laboratory Manager

Annex D. Certificates of Analysis

Order Number:	2022-005900	**Completed Date:**	01-Jul-2022
		Submitted Date:	10-Jun-2022
Submitter:	Kerri-Lynn Swanson		
Company:	Anderson Global Group		
Company Address:	2030 Main St Suite 430 Irvine, CA 92614 USA		
Results Email:	kerrilynns@andersonglobalgroup.com		
Invoice Email:	kerrilynns@andersonglobalgroup.com		
Purchase Order:	CC		

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

Order # Sample ID:	2022-005900-01	**Company:**	
Customer Sample ID:	20211101037		
Sample Description:	FiberSMART CP90 (Resistant Dextrin)		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	23-Jun-2022
	Aflatoxin B2	<1.2 ppb	23-Jun-2022
	Aflatoxin G1	<1.1 ppb	23-Jun-2022
	Aflatoxin G2	<1.6 ppb	23-Jun-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	17-Jun-2022
	Soluble Dietary Fiber Gravimetric	24.1 %	17-Jun-2022
	Soluble Dietary Fiber HPLC	63.9 %	17-Jun-2022
	Soluble Dietary Fiber Total	88.0 %	17-Jun-2022
	Total Dietary Fiber	88.0 %	17-Jun-2022
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	23-Jun-2022
	Fumonisin B2	<0.1 ppm	23-Jun-2022
	Fumonisin B3	<0.1 ppm	23-Jun-2022
Metals (DMA)	Mercury	<4.00 ppb	16-Jun-2022
Metals (ICP-MS)	Arsenic	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Cadmium	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Lead	<10 ppb	21-Jun-2022
[1] [2] Reducing Sugars	Reducing Sugars	7.2 %	24-Jun-2022
[1] [2] T2/HT2 Toxin	T-2 Toxin	<25.0 ppb	23-Jun-2022
	HT-2 Toxin	<25.0 ppb	23-Jun-2022
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.1 ppm	23-Jun-2022
	Acetyldeoxynivalenol	<0.1 ppm	23-Jun-2022
[1] [2] Zearalenone LCMS	Zearalenone	<51.7 ppb	23-Jun-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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[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

Order # Sample ID: 2022-005900-01 **Company:**
Customer Sample ID: 20211101037
Sample Description: FiberSMART CP90 (Resistant Dextrin)

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	15-Jun-2022
Coliform using Petrifilm	Coliform count	<10 CFU / g	14-Jun-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	15-Jun-2022
Mold using DRBC	Mold	<10 CFU / g	20-Jun-2022
Salmonella	Salmonella	Negative / 25 grams	01-Jul-2022
Yeast using DRBC	Yeast	<10 CFU / g	20-Jun-2022

Physical Testing

Method:	Component:	Result:	Test Date:
[2] Particle Size Distribution (Rotap)	Pan Thru Total	86.183 %	15-Jun-2022
	Sieve 1 Retained	0.037 %	15-Jun-2022
	Sieve 1 Size	10	15-Jun-2022
	Sieve 2 Retained	0.403 %	15-Jun-2022
	Sieve 2 Size	20	15-Jun-2022
	Sieve 3 Retained	1.374 %	15-Jun-2022
	Sieve 3 Size	40	15-Jun-2022
	Sieve 4 Retained	0.715 %	15-Jun-2022
	Sieve 4 Size	60	15-Jun-2022
	Sieve 5 Retained	3.683 %	15-Jun-2022
	Sieve 5 Size	80	15-Jun-2022
	Sieve 6 Retained	7.605 %	15-Jun-2022
	Sieve 6 Size	100	15-Jun-2022

[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.

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Order # Sample ID:	2022-005900-02	Company:	
Customer Sample ID:	20201002034		
Sample Description:	FiberSMART CP90 (Resistant Dextrin)		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	23-Jun-2022
	Aflatoxin B2	<1.2 ppb	23-Jun-2022
	Aflatoxin G1	<1.1 ppb	23-Jun-2022
	Aflatoxin G2	<1.6 ppb	23-Jun-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	22-Jun-2022
	Soluble Dietary Fiber Gravimetric	21.6 %	22-Jun-2022
	Soluble Dietary Fiber HPLC	65.9 %	22-Jun-2022
	Soluble Dietary Fiber Total	87.5 %	22-Jun-2022
	Total Dietary Fiber	87.5 %	22-Jun-2022
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	23-Jun-2022
	Fumonisin B2	<0.1 ppm	23-Jun-2022
	Fumonisin B3	<0.1 ppm	23-Jun-2022
Metals (DMA)	Mercury	<4.00 ppb	16-Jun-2022
Metals (ICP-MS)	Arsenic	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Cadmium	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Lead	<10 ppb	21-Jun-2022
[1] [2] Reducing Sugars	Reducing Sugars	9.5 %	24-Jun-2022
[1] [2] T2/HT2 Toxin	T-2 Toxin	<25.0 ppb	23-Jun-2022
	HT-2 Toxin	<25.0 ppb	23-Jun-2022
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.6 ppm	23-Jun-2022
	Acetyldeoxynivalenol	<0.8 ppm	23-Jun-2022
[1] [2] Zearalenone LCMS	Zearalenone	<51.7 ppb	23-Jun-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.

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

Order # Sample ID:	2022-005900-02	**Company:**	
Customer Sample ID:	20201002034		
Sample Description:	FiberSMART CP90 (Resistant Dextrin)		

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	15-Jun-2022
Coliform using Petrifilm	Coliform count	<10 CFU / g	14-Jun-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	15-Jun-2022
Mold using DRBC	Mold	<10 CFU / g	20-Jun-2022
Salmonella	Salmonella	Negative / 25 grams	01-Jul-2022
Yeast using DRBC	Yeast	<10 CFU / g	20-Jun-2022

Physical Testing

Method:	Component:	Result:	Test Date:
[2] Particle Size Distribution (Rotap)	Pan Thru Total	88.719 %	15-Jun-2022
	Sieve 1 Retained	0.179 %	15-Jun-2022
	Sieve 1 Size	10	15-Jun-2022
	Sieve 2 Retained	0.794 %	15-Jun-2022
	Sieve 2 Size	20	15-Jun-2022
	Sieve 3 Retained	1.986 %	15-Jun-2022
	Sieve 3 Size	40	15-Jun-2022
	Sieve 4 Retained	1.053 %	15-Jun-2022
	Sieve 4 Size	60	15-Jun-2022
	Sieve 5 Retained	2.999 %	15-Jun-2022
	Sieve 5 Size	80	15-Jun-2022
	Sieve 6 Retained	4.191 %	15-Jun-2022
	Sieve 6 Size	100	15-Jun-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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[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

Order # Sample ID:	2022-005900-03	**Company:**	
Customer Sample ID:	20201002024		
Sample Description:	FiberSMART CP90 (Resistant Dextrin)		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin LCMS	Aflatoxin B1	<1.3 ppb	23-Jun-2022
	Aflatoxin B2	<1.2 ppb	23-Jun-2022
	Aflatoxin G1	<1.1 ppb	23-Jun-2022
	Aflatoxin G2	<1.6 ppb	23-Jun-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.3 %	22-Jun-2022
	Soluble Dietary Fiber Gravimetric	19.2 %	22-Jun-2022
	Soluble Dietary Fiber HPLC	64.7 %	22-Jun-2022
	Soluble Dietary Fiber Total	83.9 %	22-Jun-2022
	Total Dietary Fiber	84.2 %	22-Jun-2022
[1] [2] Fumonisin LCMS	Fumonisin B1	<0.1 ppm	23-Jun-2022
	Fumonisin B2	<0.1 ppm	23-Jun-2022
	Fumonisin B3	<0.1 ppm	23-Jun-2022
Metals (DMA)	Mercury	<4.00 ppb	16-Jun-2022
Metals (ICP-MS)	Arsenic	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Cadmium	<10 ppb	21-Jun-2022
Metals (ICP-MS)	Lead	<10 ppb	21-Jun-2022
[1] [2] Reducing Sugars	Reducing Sugars	10.8 %	24-Jun-2022
[1] [2] T2/HT2 Toxin	T-2 Toxin	<25.0 ppb	23-Jun-2022
	HT-2 Toxin	<25.0 ppb	23-Jun-2022
[1] [2] Vomitoxin LCMS	Deoxynivalenol (Vomitoxin)	<0.6 ppm	23-Jun-2022
	Acetyldeoxynivalenol	<0.8 ppm	23-Jun-2022
[1] [2] Zearalenone LCMS	Zearalenone	<51.7 ppb	23-Jun-2022

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

Order # Sample ID:	2022-005900-03	**Company:**	
Customer Sample ID:	20201002024		
Sample Description:	FiberSMART CP90 (Resistant Dextrin)		

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	15-Jun-2022
Coliform using Petrifilm	Coliform count	<10 CFU / g	14-Jun-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	15-Jun-2022
Mold using DRBC	Mold	<10 CFU / g	20-Jun-2022
Salmonella	Salmonella	Negative / 25 grams	01-Jul-2022
Yeast using DRBC	Yeast	<10 CFU / g	20-Jun-2022

Physical Testing

Method:	Component:	Result:	Test Date:
[2] Particle Size Distribution (Rotap)	Pan Thru Total	87.100 %	15-Jun-2022
	Sieve 1 Retained	0.137 %	15-Jun-2022
	Sieve 1 Size	10	15-Jun-2022
	Sieve 2 Retained	0.648 %	15-Jun-2022
	Sieve 2 Size	20	15-Jun-2022
	Sieve 3 Retained	1.630 %	15-Jun-2022
	Sieve 3 Size	40	15-Jun-2022
	Sieve 4 Retained	0.785 %	15-Jun-2022
	Sieve 4 Size	60	15-Jun-2022
	Sieve 5 Retained	3.279 %	15-Jun-2022
	Sieve 5 Size	80	15-Jun-2022
	Sieve 6 Retained	6.578 %	15-Jun-2022
	Sieve 6 Size	100	15-Jun-2022

[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

Results Approved By: Elliot McSherry
(Authorized Reviewer)

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

Analytical Method References:

Method Name	Method Reference
Aflatoxin LCMS	Please contact for Method Details
Fiber (AOAC 2011.25)	AOAC 2011.25*
Fumonisin LCMS	Please contact for Method Details
Metals (DMA)	EPA 7473
Metals (ICP-MS)	AOAC: 993.14*, AOAC: 2015.06*
Reducing Sugars	Please contact for Method Details
T2/HT2 Toxin	Please contact for Method Details
Vomitoxin LCMS	Please contact for Method Details
Zearalenone LCMS	Please contact for Method Details

Micro Method References:

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

Physical Testing Method

Method Name	Method Reference
Particle Size Distribution (Rotap)	Please Contact for Method Details

* This method has been modified.

[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

Order Number:	2022-008494	**Completed Date:**	13-Sep-2022
		Submitted Date:	25-Aug-2022
Submitter:	Kerri-Lynn Swanson		
Company:	Anderson Global Group		
Company Address:	2030 Main St Suite 430 Irvine, CA 92614 USA		
Results Email:	kerrilynns@andersonglobalgroup.com		
Invoice Email:	kerrilynns@andersonglobalgroup.com		
Purchase Order:	CC		

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

Order # Sample ID:	2022-008494-01	**Company:**	Anderson Global Group
Customer Sample ID:	Lot# 20200701023		
Sample Description:	FiberSMART CS90 - Resistant Dextrin		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin	Aflatoxin B1	<1.3 ppb	12-Sep-2022
	Aflatoxin B2	<1.2 ppb	12-Sep-2022
	Aflatoxin G1	<1.1 ppb	12-Sep-2022
	Aflatoxin G2	<1.6 ppb	12-Sep-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	13-Sep-2022
	Soluble Dietary Fiber Gravimetric	3.7 %	13-Sep-2022
	Soluble Dietary Fiber HPLC	63.6 %	13-Sep-2022
	Soluble Dietary Fiber Total	67.3 %	13-Sep-2022
	Total Dietary Fiber	67.3 %	13-Sep-2022
Metals (DMA)	Mercury	<2.00 ppb	31-Aug-2022
Metals (ICP-MS)	Arsenic	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Cadmium	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Lead	<10 ppb	09-Sep-2022
[1] [2] Reducing Sugars	Reducing Sugars	14.0 %	08-Sep-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	29-Aug-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	29-Aug-2022
Mold using DRBC	Mold	<10 CFU / g	01-Sep-2022
Salmonella	Salmonella	Negative / 25 grams	30-Aug-2022
Yeast using DRBC	Yeast	<10 CFU / g	01-Sep-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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Medallion Labs
www.medallionlabs.com 800-245-5615 info@medlabs.com

Order # Sample ID:	2022-008494-02	**Company:**	Anderson Global Group
Customer Sample ID:	Lot# 20210801029		
Sample Description:	FiberSMART CS90 - Resistant Dextrin		

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin	Aflatoxin B1	<1.3 ppb	12-Sep-2022
	Aflatoxin B2	<1.2 ppb	12-Sep-2022
	Aflatoxin G1	<1.1 ppb	12-Sep-2022
	Aflatoxin G2	<1.6 ppb	12-Sep-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	0.2 %	13-Sep-2022
	Soluble Dietary Fiber Gravimetric	10.0 %	13-Sep-2022
	Soluble Dietary Fiber HPLC	61.2 %	13-Sep-2022
	Soluble Dietary Fiber Total	71.2 %	13-Sep-2022
	Total Dietary Fiber	71.4 %	13-Sep-2022
Metals (DMA)	Mercury	<2.00 ppb	31-Aug-2022
Metals (ICP-MS)	Arsenic	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Cadmium	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Lead	<10 ppb	09-Sep-2022
[1] [2] Reducing Sugars	Reducing Sugars	10.6 %	08-Sep-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	29-Aug-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	29-Aug-2022
Mold using DRBC	Mold	<10 CFU / g	01-Sep-2022
Salmonella	Salmonella	Negative / 25 grams	30-Aug-2022
Yeast using DRBC	Yeast	<10 CFU / g	01-Sep-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.

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

Order # Sample ID: 2022-008494-03 **Company:** Anderson Global Group

Customer Sample ID: Lot# 20200810013

Sample Description: FiberSMART CS90 - Resistant Dextrin

Analytical Testing

Method:	Component:	Result:	Test Date:
[1] [2] Aflatoxin	Aflatoxin B1	<1.3 ppb	12-Sep-2022
	Aflatoxin B2	<1.2 ppb	12-Sep-2022
	Aflatoxin G1	<1.1 ppb	12-Sep-2022
	Aflatoxin G2	<1.6 ppb	12-Sep-2022
Fiber (AOAC 2011.25)	Insoluble Dietary Fiber	<0.1 %	13-Sep-2022
	Soluble Dietary Fiber Gravimetric	20.0 %	13-Sep-2022
	Soluble Dietary Fiber HPLC	49.3 %	13-Sep-2022
	Soluble Dietary Fiber Total	69.3 %	13-Sep-2022
	Total Dietary Fiber	69.3 %	13-Sep-2022
Metals (DMA)	Mercury	<2.00 ppb	31-Aug-2022
Metals (ICP-MS)	Arsenic	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Cadmium	<10 ppb	09-Sep-2022
Metals (ICP-MS)	Lead	<10 ppb	09-Sep-2022
[1] [2] Reducing Sugars	Reducing Sugars	6.8 %	08-Sep-2022

Micro Testing

Method:	Component:	Result:	Test Date:
Aerobic Plate Count using PCA	Aerobic Plate Count	<10 CFU / g	29-Aug-2022
E. coli using Petrifilm	E. coli	<10 CFU / g	29-Aug-2022
Mold using DRBC	Mold	<10 CFU / g	01-Sep-2022
Salmonella	Salmonella	Negative / 25 grams	30-Aug-2022
Yeast using DRBC	Yeast	<10 CFU / g	01-Sep-2022

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

Results Approved By: Randy Vados
(Authorized Reviewer)

[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

Analytical Method References:

Method Name	Method Reference
Aflatoxin	Please contact for Method Details
Fiber (AOAC 2011.25)	AOAC 2011.25*
Metals (DMA)	EPA 7473
Metals (ICP-MS)	AOAC: 993.14*, AOAC: 2015.06*
Reducing Sugars	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	AOAC 2013.01*
Yeast using DRBC	FDA BAM CH 18*, Compendium*

* This method has been modified.

[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.

Annex E. Protein Residue Levels of FiberSMART®-Corn

Received Date: 7/27/202
Report Date: 8/4/202

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/Steve Prancevic
TEL# (949) 502-4770
FAX# (949) 502-4775

Sample Name: FiberSMART CP90
Item#
Lot# 20211006027
Lab# 396205
PO#

Analysis:	Method:	Result:	Spec:
Protein	Bradford Protein Assay	-0.12%	< 1.0%

AOAC casp Cannabis Analytical Science Program

Approved by: [redacted]

Katerina Baldwin, Lab Director

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: 5/26/2022
Report Date: 6/3/2022
Amendment date: 7/01/2022

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: Fiber Smart TP90
Item#
Lot# 202111080027
Lab# 393012
PO#

Analysis:	Method:	Result:	Spec:
Protein	LECO- combustion	N.D.	N/A
Bradford Protein Assay	Bradford Protein	<0.1%	Less Than 1%

*This is an amended report with the following updates: Result.

AOAC casp Cannabis Analytical Science Program

Approved by: Peter Heiman, Lab Director

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: 7/27/2022
Report Date: 8/4/2022

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/Steve Prancevic
TEL# (949) 502-4770
FAX# (949) 502-4775

Sample Name: FiberSMART CP90
Item#
Lab# 396204
Lot# 20211006037
PO#

Analysis:	Method:	Result:	Spec:
Protein	Bradford Protein Assay	-0.11 %	< 1.0%

casp Cannabis Analytical Science Program

Approved by: [redacted]

Katerina Baldwin, Lab Director

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FDA FORM 3667

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
000133	Oct 28, 2022
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):* _____

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 (AGG)	
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
(949) 502-4770		stevep@andersonglobalgroup.com

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

Name of Contact Person	Position or Title
Susan Cho, Ph.D.	Chief Science Officer
Organization *(if applicable)*	
AceOne RS, Inc.	
Mailing Address *(number and street)*	
5903 Hampton Forest Way	

City	State or Province	Zip Code/Postal Code	Country
Fairfax	Virginia	22030	United States of America

Telephone Number	Fax Number	E-Mail Address
301-875-6454		

SECTION C – GENERAL ADMINISTRATIVE INFORMATION

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

Resistant dextrin from corn

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 001045

☐ 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.

The intended use is same as those described in GRN 001045, resistant dextrin-tapioca; ranging from 1.2 to 10 g powders per serving: (1) baked goods; (2) beverages liquid non-dairy; (3) cereals and granola bars; (4) condiments and dressings; (5) confections; (6) dairy beverages; (7) dairy non-beverages; (8) frozen desserts; (9) gravies and sauces; (10) meal replacements; (11) pasta and grain products; (12) prepared meals and soups; (13) processed fruits; (14) shelf-stable desserts; (15) snacks and crackers; (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. The intended use levels of syrup will

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 (AGG)

(name of notifier)

has concluded that the intended use*(s)* of Resistant dextrin from corn

(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 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.

(name of notifier)

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	10/28/2022

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
	COSM_Form3667_AndersonGlobalGroupAGG_10-28-2022.pdf	Administrative
	AGGResistantdextrinfromcornGRAScoverletter10-28-22r.pdf	Administrative
	FiberSmart-cornGRAS10-28-22submittedtoFDA.pdf	Administrative

October 19, 2023

To: Officer Anderson, FDA

Subject: GRN 001133, Resistant Dextrin: Amendment

From: Susan Cho, AceOne RS

Dear Officer Anderson,

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

Question 1.
On page 16 (Table 4), you state that AOAC methods 993.14 and 2015.06 were used for the determination of arsenic, cadmium, and lead content. We note that AOAC method 993.14 is validated for the determination of trace elements in water and waste waters and AOAC method 2015.06 is validated for the determination of Na, Mg, P, K, Ca, Cr, Mn, Fe, Cu, Zn, Se, and Mo in infant formula and adult/pediatric nutritional formula. The methods are not validated for the quantification of arsenic, cadmium, mercury, and lead in food samples and thus they are not appropriate. Please provide results obtained using an appropriate method such as FDA EAM 4.7 or AOAC 2015.01. In addition, please provide the limit of detection (LOD) and the limit of quantitation (LOQ) for analytical method(s) used to analyze for heavy metals in your ingredient.

AGG's Response
AGG has requested another laboratory to run heavy metal analysis using FDA EAM 4.7 or AOAC 2015.01. The results may be available in 2-3 weeks. We will report the analytical results as well as LOD and LOQ.

Question 2.
We note that the results from the batch analyses (Tables 5-1 and 5-2, pages 16-17) demonstrate that the levels of heavy metals in your ingredient are at least 20 times lower that the proposed specification limits (Table 4, page 16). In view of FDA's Closer to Zero initiative that focuses on lowering dietary exposure to heavy metals, we recommend that you lower the heavy metals specifications to better reflect the results from the batch analyses and to be as low as possible.

AGG's Response
AGG has lowered specifications for heavy metals from <0.2 to <0.05 mg/kg. Table 4 has been revised as follows:

Revised Table 4. Specifications for AGG's Resistant Dextrin from Corn

	Powder	Syrup	Method of Analysis
Appearance	White powder		Visual
Total Dietary Fiber, g/100 g	>80	>61	AOAC 2011.25
As, mg/kg	<0.05	<0.05	AOAC 2015.01 or equivalent
Cd, mg/kg	<0.05	<0.05	
Pb, mg/kg	<0.05	<0.05	
Hg, mg/kg	<0.05	<0.05	EPA 7473
Aerobic Plate Count, CFU/g	<1,000	<1,000	FDA BAM Ch. 3
Coliform, CFU/g	<10	<10	AOAC 991.14
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.

Question *3*.
We note that in comparison with specifications provided in GRN 000436 (enzyme modified dextrin) and in the Food Chemicals Codex monograph for dextrin, your specifications for resistant dextrin from corn in Table 4 (page 16) do not include limits for mono-and disaccharides or reducing sugars, chloride, sulfur dioxide, or ash. Please discuss why limits for these constituents are unnecessary.

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 an extensive purification process.

Mono- and disaccharides (total 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 analyzed, it is expected that residual chloride content is minimal as an ion chromatography step is employed during the manufacturing process to remove anions.

The average content of total sugars (mono- and disaccharides) was less than 1.2% for both powder and syrup forms of resistant dextrin-corn. 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).

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 fewer dextrins are present). However, DE may not be relevant for a non-digestible carbohydrate polymer, such as resistant dextrin, because it is not likely that a non-digestible carbohydrate polymer 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 or non-digestible carbohydrate polymer ingredients.

Ash: The ash content in both resistant dextrin powder and syrups are expected to be below or near the detection limit of the assay of 0.12%. The presence of residual ash would not have an impact on the safety of resistant dextrin.

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

Analytical Values of AGG's Resistant Dextrin (Powder)

	Lot Number		
	20211103027	20211101037	202111006037
Ash, %	<0.012	<0.012	<0.012
Total Sugars, %	1.08	0.400	0.354

Analytical Values of AGG's Resistant Dextrin (Syrup)

	Lot Number		
	20200810013	20210318033	20210317023
Ash, %	<0.012	0.028	0.036
Total Sugars, %	0.489	0.775	0.596

Question 4.
Please confirm that all analytical methods used to test the batches manufactured using the manufacturing method described in GRN 001133 have been validated for the intended purpose.

AGG's Response
According to the Medallion Laboratory which analyzed AGG's resistant dextrin samples, all the methods of analysis have been validated.

Question 5.
On page 17, you state that the intended technical effect of resistant dextrin from corn is an ingredient. However, we note that you state that your ingredient belongs to dietary fiber category (page 11) and is intended to be used in a manner similar to other dietary fibers (page 37). Please clarify whether you intend to use resistant dextrin from corn as a source of dietary fiber. In addition, if you intend to use it for other technical effects in food, please specify these intended technical effects.

AGG's Response

Intended technical effects of resistant dextrin are as follows: 1) it is a bulking agent used in foods high in dietary fiber, 2) due to its water solubility, it provides a smooth mouthfeel in both solid and beverage foods. Although it is high in dietary fiber content, manufacturers may or may not use it as a source of dietary fiber. In summary, resistant dextrin will be used as a bulking agent or a component offering a smooth mouthfeel in foods and beverages.

Question 6.
Please confirm that all raw materials and processing aids used in the manufacturing method are used in accordance with applicable U.S. regulations, were concluded to be GRAS for the intended use, or are the subject of an active food contact notification.

AGG's Response
AGG has confirmed that all raw materials and processing aids used in the manufacturing method are used in accordance with applicable U.S. regulations, were concluded to be GRAS for the intended use, or are the subject of an active food contact notification. Resistant dextrin is manufactured under cGMP using common food industry materials and processes in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations. Process tanks and lines are cleaned with sodium hydroxide and hydrogen peroxide following standard procedures common to the dairy industry. The ion exchange resins used in the manufacturing process are food grade and comply with 21 CFR 173.25.

Question 7.
The intended uses of resistant dextrin from corn include beverages (Table 1, page 7). Please confirm that the ingredient is not intended for use in alcoholic beverages.

AGG's Response
Intended use does not include alcoholic beverages.

Question 8.
In Table 1 (page 7), you provide the use levels of resistant dextrin from corn in powder form as well as in syrup form, and you state that the use levels of the syrup are 30% higher than those for the powder. In Table 6 (page 19), you provide the estimates of dietary exposure to resistant dextrin from corn. Please clarify if the estimates in Table 6 are based on the use levels of the powder or the syrup, and provide the mean and 90th percentile eaters-only estimates of dietary exposure to the other form of your ingredient for the U.S. population aged 2 and older.

AGG's Response
The estimates in previous Table 6 were based on the use levels of the powder. After the moisture correction, the resistant dextrin content of powder and syrup are 95.16 and 73.53%, respectively. Thus, powder contains 29.4% higher resistant dextrin content compared to the syrup (95.16/73.53) or the content of resistant dextrin in the syrup is 77.27% of powder. Thus, the EDI based on powder was divided by 0.7727 to get EDIs of the syrup. The revised Table 6 includes EDIs of two forms of resistant starch, powder and syrup.

Moisture Values of AGG's Resistant Dextrin (Powder)

	Lot Number			Mean
	20211103027	20211101037	202111006037	
Moisture, %	4.25	5.23	5.03	4.84

Moisture Values of AGG's Resistant Dextrin (Syrup)

	Lot Number			Mean
	20200810013	20210318033	20210317023	
Moisture, %	28.17	24.77	26.46	26.47

Revised Table 6. EDIs of Resistant Dextrin

Population Group	All-Users Intake		EDIs of Resistant Dextrin Powder		EDIs of Resistant Dextrin Syrup	
	% Users	n	Mean	90th Pctl	Mean	90th Pctl
g/person/day						
2-5 y	99.9	996	10.2 ± 0.26	17.2 ± 0.40	13.2 ± 0.34	22.3 ± 0.52
6-12 y	99.7	1,738	11.9 ± 0.36	21.0 ± 0.61	15.4 ± 0.47	27.2 ± 0.79
13-18 y	98.7	1,416	13.1 ± 0.37	23.9 ± 0.86	17.0 ± 0.48	30.9 ± 1.11
13-18 y M	99.4	713	14.1 ± 0.54	25.9 ± 1.44	18.2 ± 0.70	33.5 ± 1.86
13-18 y F	98.1	703	12.0 ± 0.52	21.8 ± 0.82	15.5 ± 0.67	28.2 ± 1.06
19-99 y	99.0	8,277	15.1 ± 0.20	28.2 ± 0.73	19.5 ± 0.26	36.5 ± 0.94
19-99 y M	98.7	4,021	16.7 ± 0.20	31.5 ± 0.60	21.6 ± 0.26	40.8 ± 0.78
19-99 y F	99.2	4,256	13.6 ± 0.28	24.5 ± 0.62	17.6 ± 0.36	31.7 ± 0.80
2-99 y	99.1	12,427	14.4 ± 0.17	26.5 ± 0.56	18.6 ± 0.22	34.3 ± 0.72
mg/kg bw/day						
2-5 y	98.5	981	601 ± 14	1,048 ± 28	778 ± 18	1,356 ± 36
6-12 y	99.4	1,729	360 ± 12	642 ± 23	466 ± 16	831 ± 30
13-18 y	98.0	1,407	202 ± 6.2	376 ± 17	261 ± 8.0	487 ± 22
13-18 y M	99.0	711	210 ± 8.2	416 ± 28	272 ± 11	538 ± 36
13-18 y F	97.1	696	194 ± 8.8	349 ± 21	251 ± 11	452 ± 27
19-99 y	98.3	8,198	189 ± 2.8	353 ± 7.0	245 ± 3.6	457 ± 9.1
19-99 y M	97.9	3,979	193 ± 3.2	361 ± 7.5	250 ± 4.1	467 ± 9.7
19-99 y F	98.7	4,219	185 ± 4.0	347 ± 11	239 ± 5.2	449 ± 14
2-99 y	98.4	12,315	228 ± 3.5	447 ± 8.0	295 ± 4.5	578 ± 10

Based on the 2-day survey dataset from the 2017-2018 NHANES; F = females; M = males; pctl = percentile; RD= resistant dextrin; y = years.

Question 9.

On page 18, you state that "The per user 90th percentile for the various age and gender subgroups ranged from 20.2 g/day (children 1 to 6 years) to 39.3 g/day (males 19+ years) (Table 6)". We note that these estimates are not provided in Table 6. Please clarify.

AGG's Response

We thank the FDA for catching typos. We are revising the statement as follows: The per user 90th percentile for the various age and gender subgroups ranged from 17.2 g/day (children 2 to 5 years) to 31.5 g/day (males 19+ years; Table 6).

Question 10.

On page 20 you state that, "AGG's resistant dextrin-corn will currently market resistant dextrin ingredients; thus, the cumulative exposure is not expected to change." We note that the first part of this sentence appears to be incomplete. Please clarify.

AGG's Response

Thank you for catching an error. We have added the word 'replace' to the sentence. Now it reads as follows: 'AGG's resistant dextrin-corn will replace currently marketed resistant dextrin ingredients; thus, the cumulative exposure is not expected to change.'

Question 11.

On page 24, the Part 6.B.2 is titled "Mutagenicity and Genotoxicity Studies." However, no genotoxicity studies are included and described in this part. Please clarify why and state, if it is the case, that no relevant genotoxicity studies are available.

AGG's Response

We have added the following statement right after the mutagenicity studies: 'No relevant genotoxicity studies are available in the literature.'

Question 12.

The resistant dextrin ingredient is derived from corn. While corn is not considered a major food allergen in the U.S. and thus not present on the FDA's list of the 11 most common food allergens in the U.S., allergic reactions to corn and corn products have been documented in the literature. Please provide a brief discussion of this information on the potential allergenicity of corn in the narrative. Please also state your conclusion on whether allergenicity is a major safety concern from consumption of your resistant dextrin ingredient.

AGG's Response

Because resistant dextrin is a carbohydrate ingredient that contains a minimum amount of protein (less than 0.1%; please see Appendix E of the original submission), the risk of allergenicity attributed to resistant dextrin derived from corn starch is very low.

In addition, the production facility does not process any of the following known allergens: 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.

Question 13.

For the administrative record, we state the following: FDA cannot trace the journal (EC Nutrition), or the two publications from it, Case et al. (2021), and Teo and Fairchild (2021), described in the narrative section. The GRAS Final rule clearly states that the pivotal safety data should be available in the public domain. This also implies easily searchable publicly available information as a condition for general recognition. Hence, the information in these publications do not fulfill the general recognition element of GRAS conclusion. Therefore, these animal studies were not considered for the safety evaluation; rather, other information and data discussed in the safety narrative were reviewed.

AGG's Response

Thank you for the agency's comment. AGG will do its best to use or publish articles in journals which can be searched via PUBMED or Toxline.

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

Regards,

Susan Cho, Ph.D.
Chief Science Officer
AceOne RS, Inc.
Agent for AGG
scho@aceoners.com or susanscho1@yahoo.com

(301) 875-6454

COA for AGG's Resistant Dextrin Powder

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

Order # Sample ID: 2022-010258-01 **Company:** Anderson Global Group

Customer Sample ID: 20211103027

Sample Description: FiberSMART CP90 Resistant Dextrin

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	27-Oct-2022
	Saturated Fat	<LOQ %	27-Oct-2022
	Monounsaturated Fat	<LOQ %	27-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	27-Oct-2022
	trans Fat	<LOQ %	27-Oct-2022
Moisture by Vacuum Oven	Moisture	4.248 %	24-Oct-2022
Sugars	Galactose	<0.1 %	25-Oct-2022
	Fructose	<0.1 %	25-Oct-2022
	Glucose	1.08 %	25-Oct-2022
	Sucrose	<0.1 %	25-Oct-2022
	Maltose	<0.1 %	25-Oct-2022
	Lactose	<0.1 %	25-Oct-2022
	Total Sugar	1.08 %	25-Oct-2022

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

Order # Sample ID: 2022-010258-02 **Company:** Anderson Global Group

Customer Sample ID: 20211101037

Sample Description: FiberSMART CP90

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	27-Oct-2022
	Saturated Fat	<LOQ %	27-Oct-2022
	Monounsaturated Fat	<LOQ %	27-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	27-Oct-2022
	trans Fat	<LOQ %	27-Oct-2022
Moisture by Vacuum Oven	Moisture	5.232 %	24-Oct-2022
Sugars	Galactose	<0.1 %	25-Oct-2022
	Fructose	<0.1 %	25-Oct-2022
	Glucose	0.400 %	25-Oct-2022
	Sucrose	<0.1 %	25-Oct-2022
	Maltose	<0.1 %	25-Oct-2022
	Lactose	<0.1 %	25-Oct-2022
	Total Sugar	0.400 %	25-Oct-2022

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

Order # Sample ID: 2022-010258-03 **Company:** Anderson Global Group

Customer Sample ID: 202111006037

Sample Description: FiberSMART CP90 Resistant Dextrin

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	27-Oct-2022
	Saturated Fat	<LOQ %	27-Oct-2022
	Monounsaturated Fat	<LOQ %	27-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	27-Oct-2022
	trans Fat	<LOQ %	27-Oct-2022
Moisture by Vacuum Oven	Moisture	5.034 %	24-Oct-2022
Sugars	Galactose	<0.1 %	25-Oct-2022
	Fructose	<0.1 %	25-Oct-2022
	Glucose	0.354 %	25-Oct-2022
	Sucrose	<0.1 %	25-Oct-2022
	Maltose	<0.1 %	25-Oct-2022
	Lactose	<0.1 %	25-Oct-2022
	Total Sugar	0.354 %	25-Oct-2022

Analytical Method References:

Method Name	Method Reference
Ash	AOAC: 923.03*
Fat (Gas Chromatography)	AOAC: 996.06*
Moisture by Vacuum Oven	AOAC: 945.43*, 934.01*
Sugars	AOAC: 977.20*

* This method has been modified.

COA for AGG's Resistant Dextrin Syrup

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

Order # Sample ID: 2022-010258-04 **Company:** Anderson Global Group

Customer Sample ID: 20200810013

Sample Description: FiberSMART CS90

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	<0.012 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	27-Oct-2022
	Saturated Fat	<LOQ %	27-Oct-2022
	Monounsaturated Fat	<LOQ %	27-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	27-Oct-2022
	trans Fat	<LOQ %	27-Oct-2022
Moisture by Vacuum Oven	Moisture	28.166 %	26-Oct-2022
Sugars	Galactose	<0.1 %	25-Oct-2022
	Fructose	<0.1 %	25-Oct-2022
	Glucose	0.489 %	25-Oct-2022
	Sucrose	<0.1 %	25-Oct-2022
	Maltose	<0.1 %	25-Oct-2022
	Lactose	<0.1 %	25-Oct-2022
	Total Sugar	0.489 %	25-Oct-2022

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

Order # Sample ID: 2022-010258-05 **Company:** Anderson Global Group

Customer Sample ID: 20210318033

Sample Description: FiberSMART CS90

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	0.028 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	28-Oct-2022
	Saturated Fat	<LOQ %	28-Oct-2022
	Monounsaturated Fat	<LOQ %	28-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	28-Oct-2022
	trans Fat	<LOQ %	28-Oct-2022
Moisture by Vacuum Oven	Moisture	24.770 %	26-Oct-2022
Sugars	Galactose	<0.1 %	25-Oct-2022
	Fructose	<0.1 %	25-Oct-2022
	Glucose	0.775 %	25-Oct-2022
	Sucrose	<0.1 %	25-Oct-2022
	Maltose	<0.1 %	25-Oct-2022
	Lactose	<0.1 %	25-Oct-2022
	Total Sugar	0.775 %	25-Oct-2022

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

Order # Sample ID: 2022-010258-06 **Company:** Anderson Global Group

Customer Sample ID: 20210317023

Sample Description: FiberSMART CS90

Analytical Testing

Method:	Component:	Result:	Test Date:
Ash	Ash	0.036 %	21-Oct-2022
Fat (Gas Chromatography)	Total Fat	<LOQ %	28-Oct-2022
	Saturated Fat	<LOQ %	28-Oct-2022
	Monounsaturated Fat	<LOQ %	28-Oct-2022
	cis-cis Polyunsaturated Fat	<LOQ %	28-Oct-2022
	trans Fat	<LOQ %	28-Oct-2022
Moisture by Vacuum Oven	Moisture	26.464 %	26-Oct-2022
Sugars	Galactose	<0.1 %	27-Oct-2022
	Fructose	<0.1 %	27-Oct-2022
	Glucose	0.596 %	27-Oct-2022
	Sucrose	<0.1 %	27-Oct-2022
	Maltose	<0.1 %	27-Oct-2022
	Lactose	<0.1 %	27-Oct-2022
	Total Sugar	0.596 %	27-Oct-2022

Results Approved By: Steven Murray
(Authorized Reviewer)

Analytical Method References:

Method Name	Method Reference
Ash	AOAC: 923.03*
Fat (Gas Chromatography)	AOAC: 996.06*
Moisture by Vacuum Oven	AOAC: 945.43*, 934.01*
Sugars	AOAC: 977.20*

* This method has been modified.

November 8, 2023

To: Officer Anderson, FDA

Subject: GRN 001133, Resistant Dextrin: Amendment

From: Susan Cho, AceOne RS

Dear Officer Anderson,

In response to the FDA question 1, Anderson Global Group (AGG) has reanalyzed three non-consecutive lots for heavy metals using AOAC 2015.01. Eurofins has reported the limit of the limit of quantification (LOQ) as shown in the table below. Analyses of three lots demonstrated that heavy metal contents are below the LOQ. Please see the attached Eurofins memo on LOQ and certificates of Analysis (COAs).

	Lot number			
	08401-7	**17903-7**	**21703-4**	LOQ
Arsenic, ug/kg	<10	<10	<10	10
Lead, ug/kg	<5	<5	<5	5
Cadmium, ug/kg	<5	<5	<5	5
Mercury, ug/kg	<5	<5	<5	5

If you have any further questions, please contact me. We would appreciate your kind attention to this matter.

Sincerely,

Susan
Susan Cho, Ph.D.
Chief Science Officer
AceOne RS, Inc.
(301) 875-6454

Technical Datasheet

Analysis: Elements by ICP Mass Spectrometry

Aliases: 4-Heavy Metals (FS014 = USP 233 / FS017 = USP 730 / FS7CL = USP 2232) // PFSRE = Rare Earth Metals Package // Total Heavy Metals (FSLN4 = As, Pb, Cd, Hg, Cr / FS3V0 = As, Pb, Cd, Hg, Cr, Ni, V / FS015 = As, Cd, Hg, Pb / FSA0G = As, Cd, Hg) // FS4I0 = Silicon Dioxide component as well. MUST ADHOC Component and make Silicon non-reportable!! //

Code: ICP_MS_S

Scope: This method is applicable to the determination of most elements in virtually all matrices. Common nutrient minerals are typically present at higher levels and measured by ICP-OES rather than ICP-MS.

Description: Samples are digested with HNO3 in an open- or closed- vessel microwave digestion system. Analysis is performed using an inductively coupled plasma with mass spectrometric detection (ICP-MS). The digested samples are compared to standards of known concentration.

Limit of Quantitation: Typical LOQs are summarized below. LOQs may be matrix dependent.

Cadmium (Cd), Mercury (Hg), Lead (Pb), Antimony (Sb), Tin (Sn) – 5.00 ppb Arsenic (As), Cobalt (Co), Chromium (Cr), Molybdenum (Mo) – 10.0 ppb
Barium (Ba), Copper (Cu), Manganese (Mn), Nickel (Ni), Strontium (Sr) – 50.0 ppb Iron (Fe), Zinc (Zn) – 100 ppb Aluminum (Al) – 500 ppb
Sulfur (S) – 10,000 ppb

Precision: The data that support the precision (measurement uncertainty) and accuracy for this assay are on file in the Nutritional chemistry and Food Safety (NCFS) departments central files.

Sample Required: 1g

Method References: Official Methods of Analysis, Methods 2011.19 and 993.14, and 2015.01, AOAC INTERNATIONAL, (Modified).

Locations: Food Integrity Innovation-Madison - ISO Accredited

Food Integrity Innovation-Singapore - ISO Accredited

eurofins | Food Integrity & Innovation

eurofins | Food Integrity & Innovation

Report Number: 4278596-0

Report Date: 07-Nov-2023

Report Status: Final

Certificate of Analysis

Anderson Advanced Ingredients

2030 Main Street
Suite 430
Irvine California 92614 United States

Sample Name:	**AIFSBC08401-7**	**Eurofins Sample:**	**13467573**
Project ID	ANDER_AD_I-20231030-0002	**Receipt Date**	01-Nov-2023
PO Number	NA	**Receipt Condition**	Ambient temperature
Lot Number	AIFSBC08401-7	**Login Date**	30-Oct-2023
Description	FiberSMART CP90	**Date Started**	01-Nov-2023
		Sampled	Sample results apply as received
		Online Order	901-2023-E067534

Analysis	**Result**
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Lead	<5.00 ppb
Cadmium	<5.00 ppb
Mercury	<5.00 ppb

Method References	**Testing Location**
Elements by ICP Mass Spectrometry (ICP_MS_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 2011.19 and 993.14, and 2015.01, AOAC INTERNATIONAL, (Modified).

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	6304 Ronald Reagan Ave Madison WI 53704 800-675-8375

Eurofins Food Chemistry Testing Madison, Inc.

Edward Ladwig - President Eurofins Food

Chemistry Testing Madison

2918.01

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Report Number: 4275749-0

Report Date: 03-Nov-2023

Report Status: Final

Certificate of Analysis

Anderson Advanced Ingredients

2030 Main Street
Suite 430
Irvine California 92614 United States

Sample Name:	**AIFSBC17903-7**	**Eurofins Sample:**	**13467574**
Project ID	ANDER_AD_I-20231030-0002	**Receipt Date**	01-Nov-2023
PO Number	NA	**Receipt Condition**	Ambient temperature
Lot Number	AIFSBC17903-7	**Login Date**	30-Oct-2023
Description	FiberSMART CP90	**Date Started**	01-Nov-2023
		Sampled	Sample results apply as received
		Online Order	901-2023-E067534

Analysis	**Result**
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Lead	<5.00 ppb
Cadmium	<5.00 ppb
Mercury	<5.00 ppb

Method References	**Testing Location**
Elements by ICP Mass Spectrometry (ICP_MS_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 2011.19 and 993.14, and 2015.01, AOAC INTERNATIONAL, (Modified).

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	6304 Ronald Reagan Ave Madison WI 53704 800-675-8375

Eurofins Food Chemistry Testing Madison, Inc.

Edward Ladwig - President Eurofins Food

Chemistry Testing Madison

2918.01

eurofins | Food Integrity & Innovation

Report Number: 4275750-0

Report Date: 03-Nov-2023

Report Status: Final

Certificate of Analysis

Anderson Advanced Ingredients

2030 Main Street
Suite 430
Irvine California 92614 United States

Sample Name:	**AIFSBC21703-4**	**Eurofins Sample:**	**13467575**
Project ID	ANDER_AD_I-20231030-0002	**Receipt Date**	01-Nov-2023
PO Number	NA	**Receipt Condition**	Ambient temperature
Lot Number	AIFSBC21703-4	**Login Date**	30-Oct-2023
Description	FiberSMART CP90	**Date Started**	01-Nov-2023
		Sampled	Sample results apply as received
		Online Order	901-2023-E067534

Analysis	**Result**
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Lead	<5.00 ppb
Cadmium	<5.00 ppb
Mercury	<5.00 ppb

Method References	**Testing Location**
Elements by ICP Mass Spectrometry (ICP_MS_S)	**Food Integrity Innovation-Madison** 6304 Ronald Reagan Ave Madison, WI 53704 USA

Official Methods of Analysis, Methods 2011.19 and 993.14, and 2015.01, AOAC INTERNATIONAL, (Modified).

Testing Location(s)	**Released on Behalf of Eurofins by**
Food Integrity Innovation-Madison	6304 Ronald Reagan Ave Madison WI 53704 800-675-8375

Eurofins Food Chemistry Testing Madison, Inc.

Edward Ladwig - President Eurofins Food

Chemistry Testing Madison

2918.01

November 18, 2023

To: Officer Ellen Anderson, FDA

Subject: GRN 001133, Resistant Dextrin: Amendment

From: Susan Cho, AceOne RS, Inc.

Dear Officer Anderson,

In response to the FDA question number 12, Anderson Global Group (AGG) has prepared its response as follows:

FDA's question: In your response to Question 12, you stated that because corn is principally a carbohydrate and contains a minimum amount of protein (<0.1%), its ingestion cannot elicit allergic responses. However, published evidence is available in the literature that describes the occurrence of food allergies to corn (as was noted in the original Question 12 and still remains unaddressed). Therefore, please briefly summarize the information available on corn allergy, and discuss why corn allergy is not likely to pose a serious allergenicity/safety issue for the general population that will be exposed to the resistant dextrin from corn. You may address the question by (1) comparing the frequency of corn allergy to that of the major allergens, and (2) discussing whether reported cases of corn allergy are due to specific carbohydrate epitopes (if known), and whether such epitopes are relevant for the resistant dextrin.

AGG's Responses

(1) comparing the frequency of corn allergy to that of the major allergens

Researchers estimate that 33 million Americans have food allergies (approximately 10% of the population), including 5.6 million children under age 18. The table below summarizes the estimated number of Americans of all ages who have convincing symptoms of allergy to specific foods (FARE Food Allergy Facts and Stats, 2023; Available at: FARE Food Allergy Facts and Stats rev 2020-06-04.pdf; McGowan and Keet, 2013). From the National Health and Nutrition Examination Survey (NHANES), the prevalence of corn allergy obtained in the study was estimated at 0.28% among children and 0.22% among adults (McGowan and Keet, 2013) while the prevalence of allergy to other foods was estimated at approximately 10% of the population.

	Number of Americans having allergy to specific foods	% of the total U.S. population
Shellfish[1]	8.2 million	2.48
milk[1]	6.1 million	1.85
Peanut[1]	6.1 million	1.85
tree nuts[1]	3.9 million	1.18
Egg[1]	2.6 million	0.79
Fin fish[1]	2.6 million	0.79

Wheat[1]	2.4 million	0.73
Soy[1]	1.9 million	0.58
Sesame[1]	0.7 million	0.21
Corn[2]		0.22-0.28

[1]Data from Available at: FARE Food Allergy Facts and Stats rev 2020-06-04.pdf, assuming the number of total US population of 330 million.
[2]Data from studies by McGowan and Keet, 2013, based on National Health and Nutrition Examination Survey (NHANES) 2007-2010.

2) Discussing whether reported cases of corn allergy are due to specific carbohydrate epitopes (if known), and whether such epitopes are relevant for the resistant dextrin.

Oral ingestion of maize kernels can cause IgE-mediated allergic reactions (Pastorello et al., 2009). The major allergens of maize, lipid transfer proteins, are capable of inducing primary sensitization and provoking severe allergic reactions.

Maize has been found to cross-react with other cereals such as rice, wheat, and barley. Lipid transfer protein, a major allergen of maize, has shown sequence identity with lipid transfer protein of rice, wheat, and barley (Pastorello et al., 2000). A study revealed that serum from 28.5% of patients allergic to maize showed IgE binding to a 56 kDa protein granule-bound starch synthase that was present in both maize and rice but not in the oil seeds of soybeans and peanuts (Krishnan and Chen, 2013). Sera from 19 (86%) of the 22 patients allergic to maize recognized a 9-kDa protein, a lipid transfer protein (Pastorello 2000). By using immunoblotting-inhibition experiments, we demonstrated that the lipid transfer protein cross-reacts completely with rice and peach lipid transfer proteins but not with wheat or barley lipid transfer proteins. N-terminal sequence of the 16-kd allergen (recognized by 36% of patients) showed it to be the maize inhibitor of trypsin. This protein cross-reacts completely with grass, wheat, barley, and rice trypsin inhibitors; these three cereals showed cross-reactivity with trypsin-activated Hageman factor (XIIA) inhibitor and other proteins of maize (Pastorello et al., 2000).

Additionally, maize lipid transfer protein has shown sequence similarity with certain nuts (almonds, chestnuts, walnuts, hazelnuts, and peanuts), cowpeas, and fruits (apples, apricots, avocados, bananas, cherries, grapes, kiwis, papayas) (Asero et al., 2001; Carvalho et al., 2006; Conti et al., 2001; Leoni et al., 2019; Lee et al., 2005).

However, the manufacturing process of resistant dextrin-corn employs extensive purification steps resulting in an average molecular weight of 1.5 kDa. Approximately 97.5% of the total weight was achieved by degree of polymerization (DP) 40 or a molecular weight of 7.2 kDa (please see Appendix A of the original submission). Thus, the amount of residual high molecular weight proteins, such as 9-56 kDa lipid transfer protein, is expected to be trivial if any.

Overall, it is reasonable to conclude that an allergenic potential of corn starch, the raw material used in the manufacture of the resistant dextrin, is not relevant to the finished resistant dextrin ingredient.

We hope that we have properly answered the above FDA questions. We would appreciate your kind attention to this matter.

Sincerely,

Susan Cho, Ph.D.
Chief Science Officer
AceOne RS, Inc.
Agent for AGG
scho@aceoners.com or susanscho1@yahoo.com
(301) 875-6454

References

Asero R, Mistrello G, Roncarolo D, de Vries SC, Gautier MF, Ciurana CL, et al. Lipid transfer protein: a pan-allergen in plant-derived foods that is highly resistant to pepsin digestion. Int Arch Allergy Immunol. 2001;124(1-3):67-9.

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Conti A, Fortunato D, Ortolani C, Giuffrida MG, Pravettoni V, Napolitano L, et al. Determination of the primary structure of two lipid transfer proteins from apricot (Prunus armeniaca). J Chromatogr B Biomed Sci Appl. 2001;756(1-2):123-9.

Krishnan HB, Chen MH. Identification of an abundant 56 kDa protein implicated in food allergy as granule-bound starch synthase. J Agric Food Chem. 2013;61(22):5404-9.

Lee SH, Benmoussa M, Sathe SK, Roux KH, Teuber SS, Hamaker BR. A 50 kDa maize gamma-zein has marked cross-reactivity with the almond major protein. J Agric Food Chem. 2005;53(20):7965-70.

Leoni C, Volpicella M, Dileo M, Gattulli BAR, Ceci LR. Chitinases as Food Allergens. Molecules. 2019;24(11).

McGowan EC, Keet CA. Prevalence of self-reported food allergy in the National Health and Nutrition Examination Survey (NHANES) 2007-2010. J Allergy Clin Immunol. 2013;132(5):1216-9 e5.

Pastorello EA, Farioli L, Pravettoni V, Ispano M, Scibola E, Trambaioli C, et al. The maize major allergen, which is responsible for food-induced allergic reactions, is a lipid transfer protein. J Allergy Clin Immunol. 2000;106(4):744-51.

Pastorello EA, Farioli L, Pravettoni V, Scibilia J, Conti A, Fortunato D, et al. Maize food allergy: lipid-transfer proteins, endochitinases, and alpha-zein precursor are relevant maize allergens in double-blind placebo-controlled maize-challenge-positive patients. Anal Bioanal Chem. 2009;395(1):93-102.

December 11, 2023

To: Officer Anderson, FDA

Subject: GRN 001133, Resistant Dextrin: Additional Amendments

From: Susan Cho, AceOne RS, Inc.

Dear Officer Anderson,

In response to additional FDA questions, Anderson Global Group (AGG) has prepared its amendment as follows:

FDA's Additional Question a

a. In Table 4 (amendment dated October 19, 2023 and page 16 of GRN 001133), the specification for appearance of powder is stated as "white powder" whereas the specification for appearance of syrup is missing. Please provide the specification for appearance of syrup. In addition, please provide the results from the analyses of three non-consecutive batches for the powder and for the syrup to demonstrate that both forms meet their corresponding specifications for appearance.

AGG's Response

Please see the Revised Table 4. Specifications for AGG's Resistant Dextrin from Corn. Specification for appearance for powder has been changed to 'white to light yellow powder' and specification for appearance has been added for syrup as 'light yellow liquid'. In addition, certificates of analysis (COAs) for 3 non-consecutive batches of powder and syrup are attached to demonstrate that both forms meet their corresponding specifications for appearance.

Revised Table 4. Specifications for AGG's Resistant Dextrin from Corn

	Powder	Syrup	Method of Analysis
Appearance	White to light yellow powder	Light yellow liquid	Visual
Total Dietary Fiber, g/100 g	>80	>61	AOAC 2011.25
As, mg/kg	<0.05	<0.05	AOAC 2015.01 or equivalent
Cd, mg/kg	<0.05	<0.05	
Pb, mg/kg	<0.05	<0.05	
Hg, mg/kg	<0.05	<0.05	EPA 7473

Aerobic Plate Count, CFU/g	<1,000	<1,000	FDA BAM Ch. 3
Coliform, CFU/g	<10	<10	AOAC 991.14
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.

FDA's Additional Question b

b. In the response to Question 3 (amendment dated October 19, 2023), the notifier states that the ash content is expected to be below or near the detection limit (LOD) of the assay of 0.12%. However, we note that the results from the batch analyses are reported as <0.012%, i.e., below the LOD. Please clarify this.

AGG's Response

We apologize for the typo. The detection limit of the assay is 0.012%. AGG's response related to the 'ash' of Question 3 has been revised as follows:

'Ash: The ash content in both resistant dextrin powder and syrups are expected to be below or near the detection limit of the assay of 0.012%. The presence of residual ash would not have an impact on the safety of resistant dextrin.'

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

Regards,

Susan Cho, Ph.D.
Chief Science Officer
AceOne RS, Inc.
Agent for AGG
scho@aceoners.com or susanscho1@yahoo.com

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Certificates of Analysis for Appearance

Resistant Dextrin from Corn: Powder

CERTIFICATE OF ANALYSIS

Document #: FSCP90-SD003 *Approval Date:* 07 July 2022

Product Name:	FiberSMART® CP90	**Lot Number:**	AIFSBC11302-7
Item Number:	60600 (bag)	**Manufacture Date:**	23 April 2023
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	22 April 2026
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Free flowing powder	Free flowing powder
Color	Sensory	White to light yellow	White to light yellow

[redacted]

Signature

9 June 2023

Date

CERTIFICATE OF ANALYSIS

Document #: FSCP90-SD003 *Approval Date:* 07 July 2022

Product Name:	FiberSMART® CP90	**Lot Number:**	AIFSBC25301-C
Item Number:	60600 (bag)	**Manufacture Date:**	10 September 2023
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	9 September 2026
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Free flowing powder	Free flowing powder
Color	Sensory	White to light yellow	White to light yellow

Signature

30 November 2023
Date

ANDERSON ADVANCED INGREDIENTS
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fiberSMART®

CERTIFICATE OF ANALYSIS

Document #: FSCP90-SD003 *Approval Date:* 07 July 2022

Product Name:	FiberSMART® CP90	**Lot Number:**	AIFSBB34101-7
Item Number:	60600 (bag)	**Manufacture Date:**	05 April 2022
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	04 April 2024
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Free flowing powder	Free flowing powder
Color	Sensory	White to light yellow	White to light yellow

[redacted]

Signature

27 February 2023

Date

ANDERSON ADVANCED INGREDIENTS
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fiberSMART®

Certificates of Analysis for Appearance

Resistant Dextrin from Corn: Syrup

CERTIFICATE OF ANALYSIS

Document #: *FSCS90-SD002* ***Approval Date:*** *03 January 2022*

Product Name:	FiberSMART® CS90	**Lot Number:**	AIFSBC3902-9
Item Number:	60520 (tote)	**Manufacture Date:**	08 February 2023
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	07 February 2025
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Viscous liquid	Viscous liquid
Color	Sensory	Light yellow	Light yellow

Signature

Date

CERTIFICATE OF ANALYSIS

Document #: FSCS90-SD002 *Approval Date: 06 February 2023*

Product Name:	FiberSMART® CS90	**Lot Number:**	AIFSBC14302-9
Item Number:	60520 (tote)	**Manufacture Date:**	23 May 2023
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	22 May 2025
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Viscous liquid	Viscous liquid
Color	Sensory	Light yellow	Light yellow

Signature

29 June 2023
Date

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fiberSMART®

CERTIFICATE OF ANALYSIS

Document #: FSCS90-SD002 *Approval Date:* 07 July 2022

Product Name:	FiberSMART® CS90	**Lot Number:**	AIFSBC19703-9
Item Number:	60520 (tote)	**Manufacture Date:**	16 July 2023
Ingredient List:	Soluble Corn Fiber (Resistant Dextrin)	**Retest Date:**	15 July 2025
Storage Information:	Store in a properly sealed container on a pallet in a dry space (RH < 40) at ambient temperatures (< 85°F/ 29°C).		

Analysis	Test Method	Parameters	Results
Appearance	Sensory	Viscous liquid	Viscous liquid
Color	Sensory	Light yellow	Light yellow

Signature

31 August 2023
Date

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fiberSMART®

December 12, 2023

To: Officer Ellen Anderson, FDA

Subject: GRN 001133, Resistant Dextrin: Amendment

From: Susan Cho, AceOne RS, Inc.

Dear Officer Anderson,

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

FDA's 2nd request for corn allergy (11-24-23)

Discussing whether reported cases of corn allergy are due to specific carbohydrate epitopes (if known), and whether such epitopes are relevant for the resistant dextrin.

AGG's Response

Monocotyledon corn (*Zea mays*) contain carbohydrate epitopes such as callose and homogalacturonan epitopes (Giannoutsou et al., 2020). These epitopes, recognized by LM20, JIM5, and 2F4 antibodies, are mainly located in the expanding cell wall regions of the stomatal complexes (Apostolakos et al., 2021). Homogalacturonan, as a major component of pectin in the primary cell wall, is a long-chain macromolecular polysaccharide composed of repeated α-1,4-D-GalA sugar units (Guo et al., 2022). Callose, multifunctional 1→3)-β-D-glucan, has multiple roles during stomatal development and function (Apostolakos et al., 2021).

The literature has identified a few proteins (including 56 kDa, 9 kDa, and 16 kDa proteins) as the cause of corn allergy (Krishnan and Chen, 2013; Pastorello et al., 2000). Reported cases of corn allergy may be due to proteins, instead of carbohydrate epitopes.

Corn starch may have minimal amounts, if there are any, of these non-digestible polysaccharides, cell-wall components. In addition, manufacture of resistant dextrin involves extensive purification steps. Thus, it is not expected that significant amounts of carbohydrate epitopes such as callose and homogalacturonan (HG) epitopes which are mainly located in cell wall regions of stomatal complexes would be carried over to resistance dextrin (RD).

References

Apostolakos P, Giannoutsou E, Galatis B. Callose: a multifunctional (1, 3)-β-D-glucan involved in morphogenesis and function of angiosperm stomata. J Biol Res (Thessalon). 2021;28(1):17.

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Guo S, Wang M, Song X, Zhou G, Kong Y. The evolving views of the simplest pectic polysaccharides: homogalacturonan. Plant Cell Rep. 2022;41(11):2111-2123.

Krishnan HB, Chen MH. Identification of an abundant 56 kDa protein implicated in food allergy as granule-bound starch synthase. J Agric Food Chem. 2013;61(22):5404-9.

Pastorello EA, Farioli L, Pravettoni V, Ispano M, Scibola E, Trambaioli C, et al. The maize major allergen, which is responsible for food-induced allergic reactions, is a lipid transfer protein. J Allergy Clin Immunol. 2000;106(4):744-51.

We hope we have properly answered the above FDA question. We would appreciate your kind attention to our response.

Sincerely,

Susan Cho, Ph.D.
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