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December 3, 2019

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

Subject: GRAS Notification – Allulose

Dear Sir:

On behalf of Tate & Lyle., ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, allulose, 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, for addition to food.

In addition, non-safety related data and information (marked as confidential; Exhibit 2) are attached to the GRAS notice that are to be shared with the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA).

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,



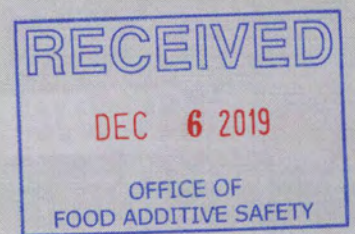
Donald F. Schmitt, M.P.H.
Senior Managing Scientist



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GRAS Determination of Allulose for Use as an Ingredient in Human Food

OCTOBER 11, 2019



ToxStrategies

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GRAS Determination of Allulose for Use as an Ingredient in Human Food

SUBMITTED BY:

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5001 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

Donald F. Schmitt, MPH
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October 11, 2019

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List of Acronyms

ADME	absorption, distribution, metabolism, and excretion
AUC	area under the curve
bw	body weight
CDC	Centers for Disease Control and Prevention
cGMP	current Good Manufacturing Practice
CAS	Chemical Abstracts Service
CEDI	cumulative estimated daily intake
CFR	Code of Federal Regulations
CFU	colony-forming units
COA	Certificate of Analysis
dpm	disintegrations per minute
FDA	U.S. Food and Drug Administration
GRAS	Generally Recognized as Safe
GRN	Generally Recognized as Safe Notification
LD ₅₀	lethal dose
NHANES	US National Health and Nutrition Examination Survey
NOAEL	no-observed-adverse-effect level
SCFA	short-chain fatty acid
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Notice Submission

Tate & Lyle (T&L), through its agent, ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for the use of allulose in selected foods for human consumption, in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

Tate & Lyle
5450 Prairie Stone Parkway
Hoffman Estates, IL 60192

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is the monosaccharide allulose.

(4) Intended Use in Food

The allulose ingredient is proposed for use as a sweetener in alcoholic beverages, meat/poultry products, grain-based cereal bars, dried cranberries, and pre-sweetened cereals. Allulose has 70% of the sweetness of sugar but provides negligible energy, and therefore is an excellent substitute for sugar to reduce sugar and energy intake.

(5) Statutory Basis for GRAS Determination

T&L, through its agent, ToxStrategies, confirms that the allulose ingredient, which meets the specifications described herein, has been determined to be GRAS through scientific procedures in accordance with 21 CFR § 570.30(a) and (b).

(6) Premarket Approval Statement

T&L further asserts that the use of the allulose ingredient, as described herein, is exempt from the pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, based on a conclusion that the substance is GRAS under the conditions of its intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent on

request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL.

(8) Data and Information Confidentiality Statement

None of the data and information in the GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

(9) GRAS Certification

To the best of our knowledge, the GRAS determination is a complete, representative, and balanced document. T&L is not aware of any information that would be inconsistent with a finding that the proposed uses and use levels of the allulose ingredient in food, meeting the appropriate specifications described herein, and used according to current Good Manufacturing Practice (cGMP), is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier



Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Tate & Lyle

12/03/2019
Date

(11) FSIS Statement

The allulose ingredient will be used as a sweetener in selected meat and poultry products at a maximum use level of 2% under the jurisdiction of USDA/SFSIS. Allulose adds a sweet flavor to meat and/or decreases saltiness.

§ 170.230 Part 2, Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

A. Identity

Allulose is produced from corn glucose by enzymatic epimerization. It contains negligible residual amounts of other related monosaccharides and impurities (Table 2 and Appendix A).

B. Common or Usual Name

D-Allulose or D-psicose. The names D-allulose and D-psicose are used interchangeably in literature but refer to the same substance. The ingredient will be referred to as allulose throughout this document.

C. CAS Registry Number

CAS No. 551-68-8

D. Trade Name

The trade name of T&L's allulose product is Dolcia Prima[®] allulose.

E. Empirical Formula and Chemical Structure of Allulose

The empirical formula for allulose is $C_6H_{12}O_6$. The chemical names are D-ribo-2-hexulose, D-ribo-2-ketohexose. The molecular weight of allulose is 180.16 g/mol. The structural formula of allulose is represented in Figure 1.

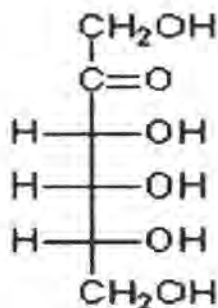


Figure 1. Structural formula of allulose

F. Allulose Composition

Dolcia Prima[®] allulose is obtained from starch derived from corn (*Zea mays* L.); see Table 1.

Table 1. Taxonomic classification of the raw material source of allulose

Classification	Corn
Kingdom	Plantae
Phylum	Magnoliophyta
Class	Liliopsida
Order	Poales
Family	Poaceae
Genus	<i>Zea</i>
Species	<i>Zea mays</i> L.

Dolcia Prima[®] Allulose is composed predominantly of allulose (> 95% in syrup version, or > 98% in crystalline version), with the remainder being composed of only a small quantity of fructose and other di- and trisaccharides typically found in syrups of sugar (Table 2).

Table 2. Composition of allulose

Components	Liquid Syrup	Crystalline
Allulose	>95%, dry basis	>99.1%, dry basis
Non-allulose saccharides	<5%, dry basis	<2%, dry basis

G. Manufacturing Process

A process flow diagram for the allulose product is shown below (Figure 2).

The starting material is typical corn (U.S. Grade #2 Dent Corn [dried grain]), and the intermediate products are monosaccharides (glucose and fructose). All enzymes used in the process are safe and suitable for food uses and consistent with enzymes identified in previous GRAS notifications (including their sources). The allulose ingredient is produced in two forms: syrup and crystalline powder. The manufacturing process is conducted under Good Manufacturing Practices (GMP) for both end products and is identical in every step but the last.

- U.S. Grade #2 Dent Corn (dried grain) is subjected to traditional wet-milling processes to produce germ, fiber, protein, and starch fractions. For the production of allulose, the starch fraction is used.
- The starch fraction (polymeric glucose; amylose and amylopectin) is converted to corn syrup (maltose and higher oligosaccharides) and ultimately to D-glucose by enzymatic hydrolysis using standard manufacturing techniques.

- D-glucose is isomerized to D-fructose using safe and suitable glucoisomerases.
- D-fructose is separated from the bulk of D-glucose by chromatography to greater than 85% (w/w) purity.
- Fructose is then epimerized to D-allulose using D-psicose 3-epimerase.
- The resulting mixture of D-allulose and D-fructose is separated by chromatography to $\geq 95\%$ D-allulose and $\leq 5\%$ non-allulose saccharides (including fructose, glucose).
- This enriched D-allulose stream is evaporated and passed through activated granular carbon and an ion exchange resin.

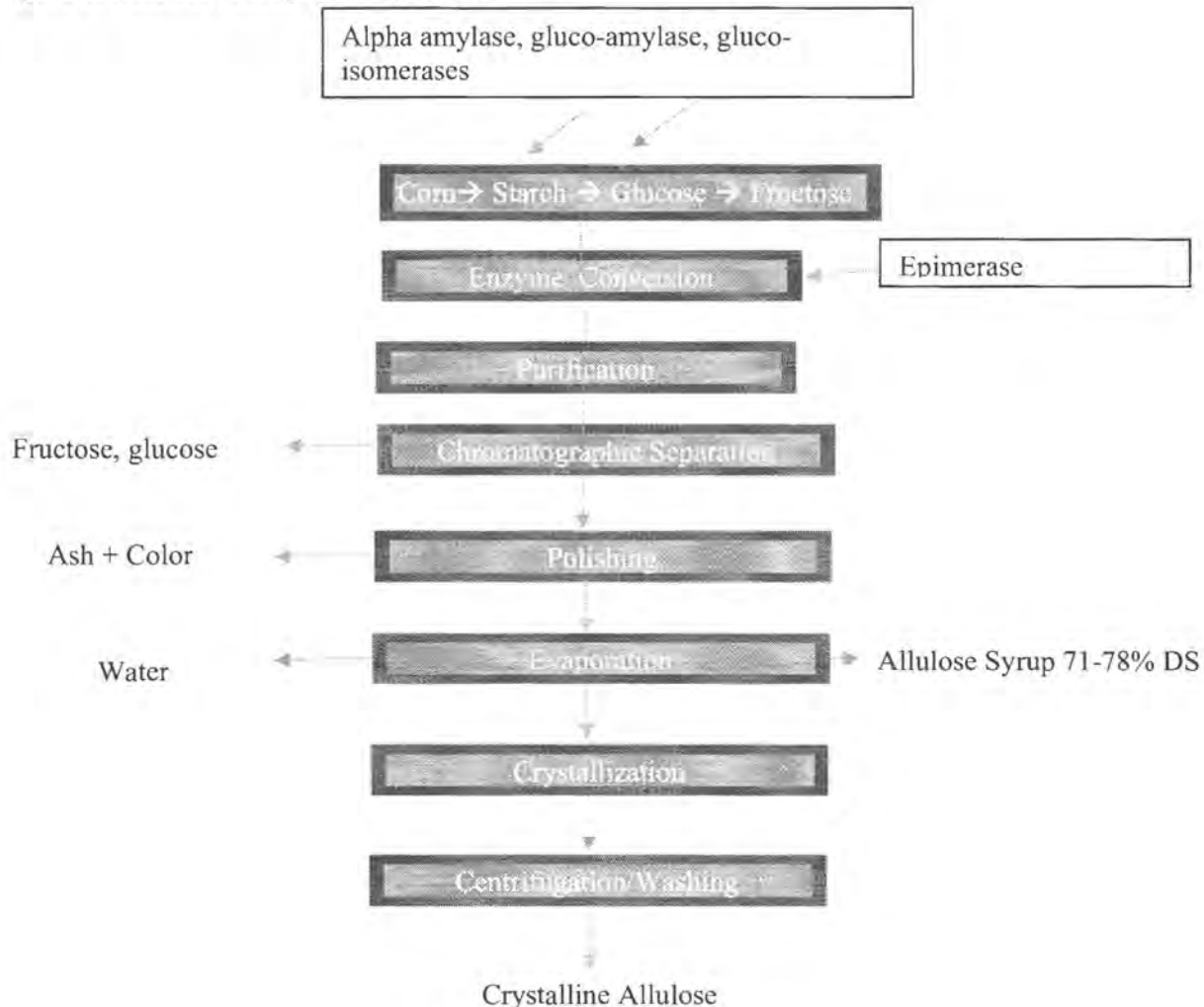
For the syrup form, the final step consists of:

Using an evaporator, the solution is concentrated to a final density of 71%–78% solids.

For the crystalline form, the final step consists of:

Using an evaporator, the solution is concentrated, crystallized, centrifuged, washed, and dried.

Figure 2. Allulose manufacturing process



All processing aids employed in the manufacturing process are safe and suitable for use in the production of food ingredients (see Table 3).

Table 3. Processing aids

Processing aid	CAS Number	Purpose	21 CFR Citations/GRN Numbers
Alpha-amylase from <i>Aspergillus oryzae</i>	9001-19-8	Hydrolysis of starch	21 CFR 172.892; 21 CFR 184.1012; GRN Nos. 22, 24, 79, 126, 594, 664, 751
Glucoamylase from <i>Aspergillus niger</i>	977031-46-1	Hydrolysis of starch	21 CFR 172.892; GRN Nos. 372, 657

Glucosiomerase from a genetically modified strain of <i>Streptomyces rubiginosus</i> (strain DP-Pzn37)	9005-00-9	Conversion of D-glucose to D-fructose	21 CFR 184.1372
D-psicose 3-epimerase from a genetically modified strain of <i>E. coli</i> K12	1219591-85-1	Conversion of D-fructose to allulose	See footnote*
Activated carbon	64365-11-3	Purification	21 CFR 175.250; 21 CFR 172.615

* The *E. coli* production microorganism is derived from the wild-type *E. coli* K12 strain. *E. coli* K-12 has a documented history of safe use. Its derivatives are currently used in a large number of drug, specialty chemical, and large-scale industrial applications including the production of amino acids for use as food ingredients. *E. coli* K12 is a nonpathogenic and nontoxic host organism and belongs to risk group 1 in the classification of human etiologic agents (NIH, 2002). It is one of the most extensively studied bacteria and has been used in genetic studies and biotechnology research in laboratories worldwide. A synthetic gene was designed and used to assure that no extraneous donor DNA was transferred to the production organism. (NIH 2002) Department of Health and Human Services, National Institutes of Health. Guidelines for Research involving Recombinant DNA Molecules, April 2002. In addition, the safety of the enzyme was based on the Pariza and Johnson Decision Tree (2001) that clearly showed that it is safe for the intended use (see Appendix A; Pariza, MW and Johnson, EA. 2001). Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century. Regul Toxicol Pharmacol 33:173-186).

All enzymes, reagents, and processing aids used in the production of allulose are safe and suitable, food grade, and in conformity with US regulations (i.e., alpha-amylase, glucoamylase, glucoisomerases, epimerase, activated carbon). They are commonly used in food ingredient manufacturing processes and all production processes used are processes traditionally used in food manufacturing.

H. Product Specifications

Specifications for the allulose product are presented in Table 4. A comparison of non-consecutive lots of product to the specifications below can be found in Tables 5 and 6. Results of analyses for additional microbiological parameters are presented in Table 7.

Table 4. Specifications for allulose

Parameter	Liquid Syrup	Crystalline Granules
Appearance	Colorless to slightly yellow	Off white
Allulose (% dry basis)	>95	>99.1
Total non-allulose saccharides (%)	<5	<2
Dry solids (%)	70-78	n/a
Moisture (%)	n/a	<1
pH	3.0 – 4.5	n/a
Ash (%)	n/a	<0.5

SO ₂ (ppm)	<10	<10
Total plate count (cfu/10g)	<200	<200
Yeast (cfu/10g)	<10	<10
Mold (cfu/10g)	<10	<10
Arsenic (ppm)	<0.1	<0.1
Cadmium (ppm)	<0.1	<0.1
Lead (ppm)	<0.1	<0.1
Mercury (ppm)	<0.01	<0.01

n/a = not applicable

Table 5. Analytical results for three non-consecutive lots of allulose syrup

Specification		Lot No. YP19DO3774	Lot No. YP19G01863	Lot No. YP18D03177
Allulose (% dry basis)	>95	96.2	96.3	96.3
Total non-allulose saccharides (%)	<5	2.6	2.9	2.4
Dry solids (%)	70-78	70.8	70.5	71.0
pH	3.0 – 4.5	4.2	3.9	4.3
Sulfur dioxide (ppm)	<10	<10	<10	<10
Total plate count (cfu/10g)	<200	<10	<10	<10
Yeast (cfu/10g)	<10	<10	<10	<10
Mold (cfu/10g)	<10	<10	<10	<10
Arsenic (ppm)	<0.1	0.016	0.011	0.024
Cadmium (ppm)	<0.1	<0.005	<0.005	<0.005
Lead (ppm)	<0.1	<0.005	<0.005	0.006
Mercury (ppm)	<0.01	<0.005	<0.005	<0.005

Table 6. Analytical results for three non-consecutive lots of crystalline allulose

Specification		Lot No. LO18J90596	Lot No. LO19F90351	Lot No. LO18J90294
Allulose (% dry basis)	>99.1	99.4	99.8	99.2
Total non-allulose saccharides (%)	<2	0.27	0.06	0.29
Moisture (%)	<1	0.14	0.12	0.10
Ash (%)	<0.5	<0.1	<0.1	<0.1
Sulfur dioxide (ppm)	<10	<10	<10	<10
Total plate count (cfu/10g)	<200	<10	10	10
Yeast (cfu/10g)	<10	<10	10	<10
Mold (cfu/10g)	<10	<10	10	<10
Arsenic (ppm)	<0.1	<0.005	<0.005	<0.005
Cadmium (ppm)	<0.1	<0.005	<0.005	<0.005
Lead (ppm)	<0.1	<0.005	<0.005	<0.005
Mercury (ppm)	<0.01	<0.005	<0.005	<0.005

Table 7. Other microbiological criteria for three non-consecutive lots of liquid syrup and crystalline allulose

Heavy Metal Limit				
Allulose Syrup		Lot No. YP19DO3774	Lot No. YP19G01863	Lot No. YP18D03177
<i>E. coli</i> (cfu/10g)	ND	ND	ND	ND
<i>Salmonella</i> (cfu/25g)	Negative	Negative	Negative	Negative
Crystalline Allulose		Lot No. LO18J90596	Lot No. LO19F90351	Lot No. LO18J90294
<i>E. coli</i> (cfu/10g)	ND	ND	ND	ND
<i>Salmonella</i> (cfu/25g)	Negative	Negative	Negative	Negative

ND = not detected

The analytical results for the allulose ingredient summarized in the above tables and included in the Certificates of Analysis (COAs) in Appendix B confirm that the finished product meets the analytical specifications. The results also demonstrate that T&L's manufacturing process results in a consistently reproducible product and confirm the lack of significant levels of impurities and/or contaminants (e.g., heavy metals, microbiological contaminants). In addition, the corn starting material is periodically

analyzed for the presence of pesticides and mycotoxins as part of Tate & Lyle's standard Quality Assurance processes.

I. Stability Data

The results of stability testing conducted using liquid allulose, Dolcia Prima[®] LS brand, at temperatures of 4°C, 25°C, and 35°C demonstrate its stability through the end of the product's shelf-life in the syrup version up to 9 months. In contrast, stability studies on Dolcia Prima[®] DS crystalline allulose show that this material is stable for up to 30 months. See Appendix C for stability testing data.

§ 170.235 Part 3, Dietary Exposure

Current Uses

Allulose is naturally present in small quantities in many common foods, such as in dried fruits (e.g., figs, raisins, fried dough, brown sugar and ketchup). Allulose amounts are usually below 1%. Table 8 describes the quantities of naturally occurring allulose in foods (Oshima et al., 2006).

Table 8. D-allulose content in foods

Item	mg/100 g food
Bakery products	
Sponge cake	11.0
Corn snack	47.0
Rice cracker	27.3
Cookie	26.7
Brown sugar drop	76.5
Fried dough cake	95.6
Chocolate chip cookies	6.4
Cereal	2.2
Dishes	
Fish broiled with soy	39.1
Simmered dishes of dried radish strips	8.1
Fermented soybeans	7.8
Seasonings and beverages	
Caramel sauce	83.0
Brown sugar	71.1
Meat sauce	15.8
Demiglace	16.3
Maple syrup	57.9
Ketchup	39.8
Worcester sauce	130.6
Coke® (sic)	38.3
Coffee	0.5
Fruit juice	21.5
Tomato juice	2.4

Item	mg/100 g food
Fruits	
Dried fig	29.6
Dried kiwi fruit	9.4
Raisin	38.7
Canned peaches	1.5
Can of mandarin oranges	8.4
Canned cherries	2.0

Allulose is approved for addition to select foods as a sweetener, per previous GRAS notifications, and these foods include bakery products, chewing gum, hard candies, frozen dairy desserts, carbonated beverages, non-carbonated beverages, soft candies, yogurt, ready-to-eat cereals, coffee mix, jams/jellies, frostings, sauces, and many others. Intake assessments of allulose in US populations were conducted as part of GRAS notification nos. 400, 498, and 693.

In GRN 400 (2012), the exposure assessment estimated the 90th percentile intakes from the intended uses of allulose to be 1.1 g/day (15.4 mg/kg bw/day) for all individuals, and 2.8 g/day (or 35.8 mg/kg bw/day) for all users of one or more foods assuming 10% of the products will be used at the maximum levels for the intended use categories.

Furthermore, if 100% of the foods had allulose added at the maximum use levels, which was considered far from a realistic situation, the 90th percentile intakes were estimated to be 11.2 g/day (0.15 g/kg bw/day) for all persons, and 28.5 g/day (0.36 g/kg bw/day) by all users of one or more foods.

In GRN 498 (2014), an intake assessment was carried out for the US market, using data from the US National Health and Nutrition Examination Surveys (NHANES) 2007–2010 dietary survey—a more traditional method than that used in GRN 400. The intake assessment considered the substitution of sugar by allulose in 14 proposed food-use categories. The assessment was carried out for five subpopulations: infants <2 years of age, children 2–12 years of age, adolescents 13–17 years of age, males 19+ years old, and females 19+ years old. The estimated daily intake (EDI) of allulose was based on foods reported to be consumed in the What We Eat in America (WWEIA) dietary component of the NHANES 2007-2010. The results indicated that the highest two-day average maximum exposure would occur in male users older than 19 years of age, with a 90th percentile value of 30.4 g/day or 0.32 g/kg bw/day. The highest intake as expressed per body weight would occur in infants < 2 years of age: 0.42 g/kg bw/day.

In GRN 693 (2017), the exposure assessment assumed that allulose would be used at the maximum levels in all of the intended food categories described in GRN 400 and GRN 498. The dietary exposure to allulose for the U.S. population (>2 years of age) was 11.0 g/day at the mean and 30.0 g/day at the 90th percentile. On a body weight basis, these estimates represented 0.16 g/kg bw/day at the mean and 0.42 g/kg bw/day at the 90th

percentile. The submitter noted that because the intended uses and use levels of allulose in the GRAS notice were a combination of those described in GRN 400 and GRN 498 for allulose, the estimated dietary exposures are slightly higher than those described in either GRN 400 or GRN 498.

Proposed Uses

The focus of this GRAS determination is for use of allulose as a sweetener in select foods that have not been previously identified in any of the publicly available GRN's (note that GRN 498 and GRN 693 did include cereals).

Table 9 below summarizes the food categories and associated use levels. An intake assessment was conducted to estimate the mean and 90th percentile daily intake of allulose based on its intended use in foods as shown in Appendix D.

Table 9. Proposed maximum food use levels

Food Category	Maximum Use Level of Allulose (%)
Alcoholic beverages (e.g., premixed cocktails, wine coolers, and malt beverages) ^a	3.5
Meat/poultry (glazed meat and poultry (e.g., ham)) ^a	5
Meat/poultry (lunchcon/formed deli meats) ^a	2
Meat/poultry (dried products such as jerky) ^a	15
Grain based cereal bars, protein bars ^b	25
Dried cranberries (i.e., Craisins) ^a	25
Condiments, major (ketchup and barbecue sauce) ^a	10
Cereal Bars ^a	25
Pre-sweetened breakfast cereal (>5% sugar) ^a	10

^a new food category; ^b new use level

Dietary Survey Data

Dietary survey data was obtained from What We Eat in America (WWEIA), the dietary interview portion of the National Health and Nutrition Examination Survey (NHANES). NHANES is carried out in two-year cycles (biennials) by the Centers for Disease Control and Prevention (CDC) in order to characterize the general health and nutritional status of children and adults across the US. The dietary intake survey portion of NHANES is a joint effort between CDC and the US Department of Agriculture (USDA). All NHANES biennials for which dietary intake data were available were included in this analysis (2003–2004, 2005–2006, 2007–2008, 2009–2010, 2011–2012, 2013–2014, and 2015–2016).

The first day of the WWEIA dietary questionnaire was administered in person, in conjunction with the participants' interviews and examinations for the other NHANES lifestyle and laboratory assessments. The second day of the survey was collected via a phone interview conducted at some point 3–10 days after the first survey day. The data set collected during the dietary interview includes foods as consumed by the participant, encoded by a food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA; only reliable respondents who also provided body-weight data were considered in this analysis.

Methods

To estimate the intake of allulose from its proposed uses, ToxStrategies performed the following steps:

- Step 1: Identified foods and their components to which allulose may be applied
- Step 2: Calculated individual intake of allulose for individual survey participants
- Step 3: Calculated population statistics estimating intake of allulose.

Details of each step are provided in the following sections.

Identification of foods and their components to which allulose may be applied

To identify foods that are proposed to contain allulose, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food-code descriptions from WWEIA were manually examined and flagged if they could be considered members of one or more of the food categories specified in Table 8. Food codes retained for further analysis are listed in Appendix C.

Calculation of individual intake of allulose for individual survey participants

Only those respondents designated as reliable were included in this assessment. Both days of the NHANES WWEIA dietary interviews from each biennial were analyzed. Participants' consumption of allulose was averaged over the two response days—i.e., (Day1 consumption + Day2 consumption)/2. Consumption of allulose was calculated using the grams of the relevant food consumed, as reported in NHANES, multiplied by the maximum proposed use level of allulose in that food. For example, for the food “25210210 Frankfurter (beef),” the maximum proposed use level was 2% (in category “Processed meat and poultry products – Formed deli meats”). Thus, a survey participant who consumed 100g of this food would consume 2 g of allulose.

Calculation of population statistics describing allulose estimated daily intake

All NHANES biennials for which dietary intake data was available were included in this analysis (2003–2004, 2005–2006, 2007–2008, 2009–2010, 2011–2012, 2013–2014, and

2015–2016). The dietary and sample weighting data from the two biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined data set, we estimated survey-design-weighted descriptive statistics for the population consumption per day. Population statistics were estimated using the “survey” package version 3.36 (Lumley, 2004; see Appendix C) in the R (version 3.6.1) environment for statistical computing (R Core Team, 2019; see Appendix C), using the appropriate adjustment to sampling weights for combining biennials, then incorporating survey sampling units and strata from the survey design to ensure that subpopulations and areas were represented correctly. Descriptive statistics (mean, 90th percentile) were calculated for the subset of consumers of allulose and for the entire population; these were broken down by age range and body-weight adjustment. Values were provided by individual food category and for total consumption of foods in all food categories.

Results

Tables 10 and 11 below, respectively, present the EDI for the extended uses of allulose in grams per day and grams per kilogram body weight per day for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older. The “number of users” refers to the number of survey participants in a given age group who consumed a food item in a given food category. The “percent users” is the percentage of allulose users out of the total number of reliable survey participants (users and non-users) belonging to a given age group. Intake is provided for each of the food categories and subcategories listed in Table 9. “Total” values include users who consumed foods in any of the proposed food categories. **Note that the “Total” values are not simple sums of the values listed above them.**

Table 10. Estimated daily intake for allulose (g/day)

Food Category	Number of Users	Percent Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90 th Percentile	Mean	90 th Percentile
US Population, Ages 2+						
Total*	36278	72.37%	3.75	8.25	2.71	7.05
US Population, Ages 2-5						
Total*	4081	88.09%	2.87	5.80	2.53	5.51
US Population, Ages 6-18						
Total*	11847	82.19%	3.88	8.21	3.20	7.57
US Population, Ages 19+						
Total*	20350	65.47%	3.80	8.50	2.60	7.05

* Total values reflect intake from foods in any of the proposed food categories

Table 11. Estimated daily intake for allulose (g/kg bw/day)

Food Category	Number of Users	Percent Users	EDI per User (g/kg/day)		EDI per Capita (g/kg/day)	
			Mean	90 th Percentile	Mean	90 th Percentile
US Population, Ages 2+						
Total*	36278	72.37%	0.07	0.15	0.05	0.13
US Population, Ages 2-5						
Total*	4081	88.1%	0.17	0.34	0.15	0.32
US Population, Ages 6-18						
Total*	11847	82.2%	0.09	0.20	0.08	0.19
US Population, Ages 19+						
Total*	20350	65.5%	0.05	0.12	0.03	0.09

* Total values reflect intake from foods in any of the proposed food categories.

The population group *per user* 90th percentile intakes ranged from 5.8 to 8.5 g/day, with the highest overall *per user* 90th percentile intake being in the 19+ age group and the lowest in the 2- to 5-year age group. The population group *per user* 90th percentile intakes normalized for body weight ranged from 0.12 to 0.34 g/kg bw/day, with the highest overall *per user* 90th percentile intake being in the 2- to 5-year age group and the lowest in the 19+ age group. Compared to intake assessments in previous GRAS notifications, the addition of allulose to the new food categories represents an intake of 5.8–8.5 g/day by a 90th percentile intake allulose consumer. Given a previously estimated daily intake of approximately 30 g/day (e.g., GRN 693), the cumulative estimated daily intake (CEDI) is approximately 35.8–38.5 g/day when considering extended uses of allulose proposed in this notification.

The estimate of the 90th percentile *per user* consumption for the general US population (2+ years of age) of approximately 8.25 g/day, or 0.15 g/kg bw/day and the CEDI are extremely conservative. In reality, the actual consumption would be much less, because the intake assessment assumes that individuals consume all the listed foods daily, and in some cases, the allulose would be present in only a subcomponent of an identified food. As a conservative assumption, however, allulose was assumed to be present in 100% of each identified food. Furthermore, a 2-day survey overestimates the actual consumption. As reviewed by Lambe and colleagues (2000), shorter surveys are associated with misclassification of individuals, inaccurate correlation coefficients, reduced power, and overestimation of the percentages of high and low intakes. The effects of survey duration are thought to be due to the within-person and day-to-day variation. In addition, the percentage of respondents who consume a food increases as survey duration increases, because the longer duration begins to incorporate days with no consumption, thus decreasing the mean intakes among consumers over time.

§ 170.240 Part 4, Self-Limiting Levels of Use

The use of allulose in foods is considered to be self-limiting, for technological reasons such as product flavor profile, which could affect consumer acceptability.

§ 170.245 Part 5, Experience Based on Common Use in Food

The statutory basis for our conclusion of the GRAS status of allulose for the proposed food uses in the notice is based on scientific procedures and not common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval

Allulose is considered GRAS for use in selected foods for human consumption (FDA, 2012, 2014, 2017; Table 12). Extensive published information and data have been submitted to and reviewed by FDA as part of the various GRNs for allulose ingredients.

Table 12. Regulatory approvals for use of allulose in human food

Year Approved	Country	Submission
2012	USA	GRN 400; D-psicose
2014	USA	GRN 498; D-psicose
2017	USA	GRN 693; D-psicose
—	USA	GRN 828; D-psicose (pending)
2015	Mexico	Allulose as a non-nutritive sweetener
2015	Chile	Allulose as an ingredient
2017	Columbia	Allulose as an ingredient
2017	Costa Rica	Allulose as a food ingredient
2017	South Korea	Allulose as a “processed saccharide product”
2017	Singapore	Allulose as a food ingredient

Safety

Introduction

Allulose has been added to food as an alternative sweetener and has a history of safe use. Multiple GRAS “no questions” letters have been issued (GRNs 400, 498, 693) with respect to the conclusion regarding the safety of the intended uses and use levels of allulose in foods in which it serves as a sugar replacer/sweetener at levels up to 100% (FDA, 2012, 2014, 2017). Clinical and preclinical studies with allulose have been conducted to examine its general toxicity and gastrointestinal tolerance and are summarized in the following sections, many similar references and discussion can also be found in the GRNs noted above (Tables 13 and 14).

Absorption, Distribution, Metabolism, and Excretion (ADME)

GRN Nos. 400 498, and 693 have previously reviewed and summarized the ADME properties of allulose. Human studies have reported that allulose is rapidly absorbed in

the small intestine and is mostly excreted in urine within 48 hours, although it is not significantly metabolized (Iida et al., 2010). Additionally, several rodent studies indicate that allulose is absorbed after oral administration and eliminated after both oral and intravenous administration (Matsuo et al., 2003; Tsukamoto et al., 2014; Whistler et al., 1974).

Animal studies

Whistler et al. (1974) conducted a study with intravenous administration of 15 mg of ¹⁴C-labeled allulose to rats (150–200 g bodyweight), collecting urine samples and carbon dioxide exhaled for six hours following the intervention for analysis. It was demonstrated that only 0.6% of the monosaccharide was excreted through respiration; the vast majority (97%–98%) was eliminated through the urine (35.4%), which suggests that the allulose is metabolized in small quantities and eliminated very quickly through the kidneys. In the same study, following oral administration of the monosaccharide, about 70% was excreted in the urine in the first 7 hours, demonstrating that allulose passed through the wall of the small intestine and as in the intravenous administration, entered the bloodstream and was eliminated primarily by the kidneys (Whistler et al., 1974).

Following oral administration to Wistar rats, Matsuo et al. (2003) investigated the absorption, excretion, and fermentation of allulose. In the absorption test, 18 animals (6 weeks old; average weight 140 ± 4 g) were given a single dose of 5 g/kg bw of allulose, then divided into three groups for the collection of blood samples and quick removal of the organs at 1, 3, and 7 hours after ingestion (Matsuo et al., 2003). A progressive reduction in the serum concentration of allulose was observed, with a more pronounced drop after the first hour, as well as in the level contained in the small intestine, with quantities of the monosaccharide being detected at 6%–10% after 1 hour, 2%–3% after 3 hours, and 1%–3% after 7 hours. In the stomach, levels of 26%–37% were found after 1 hour, 0.4%–0.6% after 3 hours, and nothing after 7 hours post-intervention. By comparison, in the cecum, despite not having been detected after the first hour, there was an increase in the concentration of the monosaccharide after 3 (11% to 18%) and 7 hours (10% to 19%) (Matsuo et al., 2003).

Tsukamoto et al. (2014) administered ¹⁴C-labeled D-psicose intravenously and by oral gavage at a dose of 100 mg/kg bw to Wistar rats. After oral administration, D-psicose appeared rapidly in the bloodstream, while peak liver and kidney concentrations occurred 60 minutes post-administration. At 120 minutes, D-psicose concentrations decreased in the liver and kidney and were highest in urine, indicating rapid elimination (Figure 3). Seven days after oral administration, the appearance of D-psicose in the body was less than 1% of the original dose. Following intravenous administration, the D-psicose concentration in the blood was decreased with a half-life of 57 minutes, and the excretion in urine was approximately 50% within 1 hour. Similar to the results obtained following oral administration, accumulation in organs was primarily in the liver (Tsukamoto et al., 2014).

In an excretion test conducted by Matsuo et al. (2003), samples of urine and feces were collected at 24-hour intervals for three days from eight Wistar rats, six weeks old, and having an average weight of 138 ± 4 g, that had been given a single dose of 5 g/kg bw of allulose. Twenty-four hours after administration, 11%–15% of the quantity ingested was detected in the urine, and 8%–13% in the feces. In the following two periods (48 and 72 hours), no additional residual monosaccharide was found, thus suggesting that practically all of the allulose was eliminated during the first hour.

Human studies

In a study by Iida et al. (2010), following oral ingestion of 0.08, 0.17, or 0.33 g/kg bw of D-psicose, excretion rates in urine were measured for up to 48 hours in 14 humans. In the first 12 hours, urine excretion rates ranged from 54% to 63%, depending on dose, then decreased to 3% to 6% by 24 to 48 hours following administration. Cumulative excretion rate measured at 48 hours for the lowest dose (0.08 g/kg bw) was $78.8\% \pm 11.7\%$, whereas the 0.33-g/kg bw dose was $66.2\% \pm 12.6\%$ (Iida et al., 2010).

To evaluate the absorption, distribution, metabolism, and excretion (ADME) of allulose in humans, a single dose containing 15 g Dolcia Prima® allulose containing a defined quantity of marked [$^{14}\text{C}(\text{U})$] allulose was administered to eight healthy male adult individuals (Atiee, 2015; unpublished). In the first 6 hours after ingestion, exhaled air, as well as samples of blood, urine, and feces, were collected at previously established times over the course of the first 7 days. Analytical results from the blood samples showed that the monosaccharide was absorbed quickly, with the maximum mean plasma concentrations reached in the first hour after ingestion (Atiee, 2015; unpublished).

Work in humans by Atiee, 2015 (unpublished), suggested further that allulose is not metabolized for energy in humans as only 6% of a total of 80 samples of exhaled air collected following the administration of ^{14}C -labeled allulose showed detectable levels of measurable $^{14}\text{CO}_2$. Levels above the minimum detection limit of the equipment (50 disintegrations per minute [dpm]). Of the five samples with detectable levels of measurable $^{14}\text{CO}_2$, the highest concentration found was only 79.29 dpm which indicated that allulose is not metabolized for energy in humans (Atiee, 2015; unpublished).

After analysis of human samples of urine and feces, collected following the administration of ^{14}C -labeled allulose, Atiee, 2015 (unpublished) confirmed that the urinary tract represents the primary route of allulose elimination. For seven participants, 84% to 93% of the ingested dose was recovered in the urine and feces samples. Only one individual showed very low recovery in the urine, less than 50% of the marked ^{14}C , when compared to all of the other participants. This was most likely due to incomplete urine collection by this subject who was therefore considered to be an outlier of the group studied (Atiee, 2015; unpublished).

The ADME studies described above demonstrate that there are similarities in how allulose is absorbed, metabolized, and eliminated from the body in both animals and humans.

Animal Studies

Acute Toxicity

The acute toxicity of allulose was investigated by Matsuo et al. (2002a). Five groups of eight male Wistar rats each were administered a single oral dose of allulose (8, 11, 14, 17, or 20 g/kg bw). Three rats receiving 14 g/kg bw, three rats receiving 17 g/kg bw, and eight rats receiving 20 g/kg of allulose died within 2 days of allulose administration. The authors calculated the LD₅₀ value of 16.3 g/kg by the Behrens-Karber method and 15.8 g/kg by the Litchfield-Wilcoxon method.

These LD₅₀ values are of the same magnitude as for other commonly consumed carbohydrates (e.g., fructose [14.7 g/kg-bw] and erythritol [15.3 g/kg-bw]). Compounds with LD₅₀ values of >5 g/kg bw in rats are classified as “practically non-toxic,” and compounds with LD₅₀ values of >15 g/kg bw as “relatively harmless” (Altug, 2003).

Nishi et al. (2016) conducted a study in dogs, reporting that a single oral dose of 1 or 4 g/kg bw allulose did not cause any treatment-related abnormalities in dogs. All dogs were active and had good appetites throughout the study period. Blood glucose concentrations decreased slightly, without a rise in plasma insulin concentration 2 hours after D-allulose administration. Plasma alkaline phosphatase activities showed a mild and transient increase between 12 and 48 hours after D-allulose administration. The data suggest that a single oral dose of up to 4 g/kg bw of D-allulose does not result in severe toxicity in dogs.

Subchronic toxicity

A 90-day oral sub-chronic toxicity study was undertaken with allulose (Matsuo et al., 2012). In this study, male Wistar rats (3 weeks old) were fed diets containing 3% allulose or sucrose for 90 days. The body-weight gain and intra-abdominal adipose tissue weight did not differ between the sucrose and the allulose groups. The weights of the liver and kidneys were significantly higher in the allulose group than in the sucrose group. However, no gross pathological findings were evident at dietary doses of 3% allulose or were correlated with hypertrophy of the liver and kidney. The erythrocyte and leukocyte counts were observed to be statistically higher in the allulose group, but the authors concluded that the differences from the control group were small and considered not toxicologically significant. Therefore, the authors concluded that no adverse effects were shown, and the authors derived a NOAEL for allulose as 3% of the diet (equivalent to 1,670 mg/kg bw/day) which was the highest level tested.

Another 90-day oral sub-chronic toxicity study was undertaken to investigate a high allulose syrup (85%) in male Wistar rats (Matsuo and Ishii, 2011), as compared to the previous study diet containing 3% of allulose (see above Matsuo et al., 2012). The body-weight gain and intra-abdominal adipose tissue weight did not differ between the control and allulose group. Also, weights of the tissues did not differ. In clinical chemistry and hematological analyses, no differences were found. No gross pathological findings were evident at dietary doses of 4.3% allulose syrup (approximately 2,000 mg/kg bw/day). The

authors conclude that similar to the 3% allulose (powder) diet, a diet containing 85% concentrated allulose syrup (average 3.7% allulose) did not induce any adverse effects.

Sub-chronic toxicity was assessed in a 34-day feeding study in 4-week-old Wistar rats (Matsuo et al., 2002a). Eight groups of seven male Wistar rats were fed a diet containing 0 (control), 10%, 20%, 30%, and 40% allulose. One rat on the 30% allulose diet and five rats on the 40% allulose diet died during the experimental period. It should be noted that the 30 and 40% dietary levels administered were extremely high, resulted in the deaths described above, and can be considered inappropriate for a toxicity study of this design. Higher concentrations of allulose resulted in decreased body weight gain and food efficiency. The authors concluded that the decreases in body weight gain in the 10% and 20% groups were attributable to a decrease in food intake and were not considered to be of toxicological significance. A laxative effect was noted but was transient and was not observed after 4 days. Rats fed the 30% and 40% allulose diet were able to regain body weight and food intake during the first 7 days of the feeding period, suggesting that the effects may have been transitory. The authors reported that allulose concentrations of up to 20% of the diet did not show adverse effects.

Chronic toxicity

Long-term toxicity of allulose was investigated by Yagi and Matsuo (2009) in male Wistar rats receiving a diet containing 3% allulose (or 1,280 mg/kg bw/d) or 3% sucrose (1,220 mg/kg bw/day) for 12–18 months. The authors found that allulose administration resulted in a lower body-weight gain and lower intra-abdominal adipose tissue weight than in rats fed the sucrose diet. Relative weights of liver and kidney were significantly higher in the allulose group than in the sucrose group, but this was not considered toxicologically significant. General hematology or serum chemistry tests were within the normal ranges for all animals and did not differ between the sucrose and allulose groups. Hemoglobin (Hb) and mean corpuscular volume (MCV) at 18 months were significantly greater in the allulose group than in the sucrose group, but no differences were observed in any of the related hematology values. The histopathological data demonstrated that there were no toxicologically significant findings in rats fed 3% allulose. The authors concluded that administration of allulose at 3% in the diet for 12–18 months (1,280 mg/kg bw/day) did not result in any adverse effects in rats.

Table 13. Summary of the toxicity studies supporting the safety of allulose

Animals	Doses	Duration	Endpoints Evaluated	Results Found	Reference
Dogs	1 and 4 g/kg bw	One day by gavage	Acute toxicity-food intake and selected clinical chemistry	Safe up to the tested dose of 4 g/k bw	Nishi et al. (2016)
Male <i>Wistar</i> rats	8, 11, 14, 17 & 20 g/kg bw	One day by gavage	Acute toxicity	LD ₅₀ = 16,3 g/kg bw	Matsuo et al. (2002a)
Young <i>Wistar</i> rats	10%, 20%, 30% and 40% in the diet	34 days	Food intake, weight gain, and organ weights	No adverse effects reported up to 20% in diet	Matsuo et al. (2002b)

Male <i>Wistar</i> rats	3.0% or 4.3% in the diet	90 days	Serum biochemistry, hematology, histology, and macroscopic exams	Safe up to the tested dose of 4.3% (estimated to be approx. 2 g/kg bw/d)	Matsuo and Ishii (2011)
Male <i>Wistar</i> rats	3.0% (1.67 g/kg bw/d) in the diet	90 days	Serum biochemistry, hematology, histology, and macroscopic exams	Safe at the tested dose of 3% (1.67 g/kg bw/d)	Matsuo et al (2012)
Male <i>Wistar</i> rats	3.0% (1,280 mg/kg bw/d) in the diet	12-18 months	Food intake, weight gain, organ weights; serum biochemistry, hematology, histology	Safe at the tested dose (NOAEL >1,280 mg/kg bw/d)	Yagi and Matsuo (2009)

Reproductive toxicity

Kim et al. (2019) evaluated the reproductive toxicity of D-allulose in rats. They assessed reproduction and offspring growth following gavage administration of D-allulose to parental rats at dosage levels of 0, 500, 1000, and 2000 mg/kg-bw. Female rats were dosed continuously from 2 weeks prior to mating until day 21 of lactation, while males were dosed for the 10-week period before mating. No direct toxicity or mortality was evident following D-allulose administration, and no changes in body weight or food consumption were observed in the test article or control groups. No significant alterations in precoital time, copulation index, fertility index (male), or pregnancy index (male) were observed between groups. Relative to the control group, there was also no effect of D-allulose treatment on pregnancy rates, implantation, pregnancy length, gender ratios, viability indexes, lactation indexes, prenatal death rates, or the number of live young at time of birth. Organ weights and associated indexes were also comparable between groups at the time of sacrifice, and treatment with D-allulose was not linked to any obvious manifestations on necropsy or histopathological examination. In the F1 generation offspring, the body weights of pups born to parents administered D-allulose (500, 1000, and 2000 mg/kg-bw) were slightly higher on days 1–9 postnatally, relative to controls ($p < 0.05$); however, after day 9, the body-weight effects were no longer evident. The NOAEL for D-allulose was considered to be 2000 mg/kg-bw, the highest dose level tested, for both parental animals and their offspring.

Mutagenicity/genotoxicity

GRN 400 included the results of an Ames test that did not find evidence of mutagenic potential, and also reported on both a micronucleus test and chromosomal aberration test that found no evidence of genetic toxicity following exposure to allulose.

As yet unpublished studies of mutagenicity and genotoxicity were conducted *in vitro* and are considered supportive of the lack of genotoxicity of allulose as demonstrated in previous allulose GRNs (Nos. 400, 498, 693). The results of an Ames assay and micronucleus test did not show any evidence of mutagenic or genotoxic potential (Li, 2015-unpublished; Neft, 2015-unpublished).

Human Studies

Clinical studies conducted in humans have also evaluated the tolerability and occurrence of adverse effects related to consumption of allulose by healthy populations.

In general, the studies demonstrated the acceptability of different quantities of allulose. Like other ingredients, such as polyols and other monosaccharides (e.g., fructose, tagatose), or as fibers and some digestion-resistant oligosaccharides, the consumption of large quantities of the ingredient can cause certain gastrointestinal discomfort, this effect being a temporary symptom of the adaptation of the gut flora and therefore without toxicological significance.

Previously, and even at the beginning of the 20th century, it was very common to consume greater quantities of raw, whole foods and foods rich in non-digestible fiber and carbohydrates, and the gastrointestinal systems of the population were better adapted to dealing with high concentrations of such compounds without presenting any temporary symptoms or discomfort through the ingestion of high doses (e.g., 120–160 g/day; Leach and Sobolik, 2010; Shoemaker, 1927). Over time, due to changes in eating habits and lifestyle, and with a significant reduction in the ingestion of fiber and other non-digestible carbohydrates, there has been a proportional reduction in the tolerance levels of the gut flora to the consumption of non-digestible ingredients.

More recent studies have demonstrated the ability of the gut flora to adapt to various levels of allulose over time, such as the clinical study of Iida et al. (2007) summarized below, which observed good tolerability for daily consumption of up to 31.0–33.3 g/day of allulose in healthy individuals.

Han et al. (2018) investigated gastrointestinal tolerance in 30 healthy adults (15 males and 15 females), ages 21–30 years old. Two experiments were conducted. In the first experiment, the study participants were given daily single doses of allulose starting at 0.1 g/kg bw/day and increasing by 0.1 g/kg bw/day every week until gastrointestinal symptoms were observed, at which time the study was terminated. In the fifth week, some participants developed gastrointestinal symptoms, and the study was stopped. The maximum tolerated dose in this study was 0.4 g/kg bw/day (when all of the allulose was consumed as a single dose). This maximum tolerated single dose was then used by Han et al. (2018) to conduct a second study in which the same protocol was followed as the first study, with the difference that, this time, the allulose was consumed in portions throughout the day, similar to how meals and snacks are consumed by people. In this case, the maximum tolerated dose was 0.9 g/kg bw/day, or about 63 g/day for a 70-kg adult.

Iida et al. (2007) investigated the effects of the use of allulose on gastrointestinal symptoms in five healthy men and five healthy women, aged between 20 and 30 years. For this purpose, all of the volunteers were given, at the beginning, 0.4 g/kg bw/day of allulose, increasing 0.1 g/kg bw/day up to a maximum of 0.9 g/kg bw/day, for six days. All of the test sample was consumed by the participants in a single sitting during the day. While two participants did not report any adverse effects, even at the highest doses, some

cases of diarrhea were reported with the administration of doses between 0.6 and 0.8 g/kg bw/day: one man ingesting 0.6 g/kg bw/day, two women at 0.7 g/kg bw/day, and two men and three women at 0.8 g/kg bw/day. The study concluded that the maximum tolerance levels were 0.5 g/kg bw/day (or 33.3 g/day), for men, and 0.6 g/kg bw/day (or 31.0 g/day), for women.

This clinical study of Iida et al. (2007) established a dose-response relationship for the onset of diarrhea in humans, showing that in men the maximum tolerated dose was 0.5 g/kg bw, whereas in women, it was 0.6 g/kg bw (above these doses, gastrointestinal effects such as abdominal pain, gas formation, and diarrhea occurred). Thus, it was established that, for humans, the NOAEL for allulose is 0.5 g/kg bw (33.3 g/day) for men and 0.6 g/kg bw (31 g/day) for women (Iida et al., 2007; FDA, 2012, 2014, 2017).

It is noteworthy that these no-effect levels for human subjects from Iida et al. (2007) are based on single doses of allulose, where the daily dose was consumed completely in one sitting. The actual threshold is even higher if the allulose was consumed in portions throughout the day, as one would when consuming meals and snacks daily (Han et al., 2018).

Another clinical safety study of long-term use was performed with 17 healthy volunteers, evaluating the effects of consuming 15 g/day of allulose (n=8) or glucose (n=9) for 12 consecutive weeks. According to the results observed, there were no adverse effects or changes in several hematological and biochemical parameters used in clinical toxicology studies (Hayashi et al., 2010). Four years later, a randomized, double-blind clinical trial in 34 individuals (n=17 each for allulose and control groups) evaluated the effect of 30 g/day of syrup containing 6% allulose (i.e., 1.8 g/day of allulose) and various amounts of other sugars for 12 weeks. During the treatment phase, the subjects consumed either a test drink or a control drink 30 minutes before breakfast on a daily basis. No adverse effects were found in relation to hepatic and renal function, nor any alterations in the biochemical and hematological parameters of the group consuming 1.8 g/day of allulose (Hayashi et al., 2014).

A typical dose of allulose (0.35 g/kg bw, in 100 mL solution) during a clinical study with healthy volunteers revealed that intestinal absorption may range from 66.2% to 80% of the dose initially ingested, while not being converted to energy. The absorption rate of different types of sugars correlates well with the provided laxative effect and the consequent no-observed-effect level. This is because the lower the absorption rate, the greater the intestinal fermentation and, consequently, the laxative effect, hence, lowering the no-effect level. For sorbitol, for example, which has a low intestinal absorption rate, the NOAEL is 0.15–0.17 g/kg bw for men, and 0.24–0.30 g/kg bw for women. For erythritol, which is better absorbed in the small intestine (90%), the NOAEL for tolerance is 0.66 g/kg bw for men, and 0.8 g/kg bw for women. Therefore, with an absorption rate slightly lower than that of erythritol, allulose would also be expected to have a slightly lower threshold for GI intolerance. This is reflected in the previously accepted NOAEL of 0.6 g/kg bw/day for allulose GI tolerance for both men and women.

In summary, the studies (Table 14) demonstrated the tolerability of different quantities of allulose. Like other ingredients, such as polyols and other monosaccharides (e.g., fructose, tagatose), or fibers and some digestion-resistant oligosaccharides, the consumption of large quantities of the ingredient can cause certain gastrointestinal discomfort; this effect is a temporary symptom of the organism adapting and therefore is without toxicological significance.

Table 14. Clinical trials conducted with administration of Dolcia Prima® allulose

References	Main Characteristics of the Human Studies on Allulose	Doses with No Adverse Effects in Human Subjects
Human Studies on Allulose		
Iida et al. (2008)	<ul style="list-style-type: none"> - Total combined n=28; - Doses 0, 2.5, 5.0, and 7.5 g; - Ages 20–39; - Healthy individuals (male and female). 	7.5 g (highest single dose tested)
Hayashi et al. (2010)	<ul style="list-style-type: none"> - n=17; - Healthy individuals-men and women-given allulose (n=8) or glucose (n=9); - Dose 15 g/day, for 12 weeks. 	15 g/day (one dose level tested)
Iida et al. (2007)	<ul style="list-style-type: none"> - n=10 (5 males and 5 females); - Age 20-30 years; - Given 0.4–0.9 g/kg bw/day in increments of 0.1 g/kg bw/day; - Dosing was once a day at 10 am, followed by 1 week of no allulose ingestion, and then the higher dose was consumed; - 6 treatment days, over 6–7 weeks. 	Up to 0.5 g/kg bw/day was tolerated well by men, and 0.6 g/kg bw/day was tolerated well by women, when consumed as a single dose. This equates to up to 33.3 g/serving, for men and 31 g/serving for women (based on the study participants, or about 35–42 g/serving for 70-kg bw adults in general)
Hayashi et al. (2014)	<ul style="list-style-type: none"> - N=34 (males and females; 17 in allulose group and 17 in control group) - Given 1.8 g/day of allulose in 30 g of syrup, over 12 weeks. 	1.8 g/day (one dose level tested)
Han et al. (2018)	<ul style="list-style-type: none"> - n=30 (15 males and 15 females); - Age 21-30 years; - Given daily doses of allulose increasing every week until gastrointestinal symptoms observed; - Study duration about 8 weeks, for allulose consumption throughout the day, and about 5 weeks, for single daily dose exposures. 	0.9 g/kg bw/day, or 63 g/day, for a 70-kg bw adult, when allulose is consumed in portions throughout the day, 0.4 g/kg bw/day, or 28 g, for a 70-kg bw adult well-tolerated, as a single bolus dose consumed at one time.
Human Studies on Dolcia Prima® Allulose		
Kendall et al. (2014)	<ul style="list-style-type: none"> - n=10; - Healthy subjects given allulose or glucose. 	25 g (single dose tested)
Wolever et al. (2014)	<ul style="list-style-type: none"> - n=12 healthy adults; N=12 adults with type II diabetes - Given allulose or glucose. 	25 g (single dose tested)
Noronha et al. (2018)	<ul style="list-style-type: none"> - n=24; - Given single doses of 0, 5.0 or 10 g allulose, in a solution containing 75 g glucose. 	10 g (highest dose tested)

Effect on Insulinemic and Glycemic Response

In addition to the more classical ADME studies, other clinical studies and experiments on animals have been conducted to observe the effects of allulose on glycemia and/or insulinemia.

Animal studies

Matsuo and Izumori (2009) conducted a research study on the effects of allulose on the postprandial glycemic response in 6-month-old male Wistar rats. Animals were given 2.0 g/kg bw of sucrose, maltose, or soluble starch supplemented with 0.2 g/kg bw of allulose or fructose. An inhibitory effect of allulose was observed on the glycemic response of the other sugars, significantly suppressing the increase in glycemia that normally occurs after the ingestion of carbohydrates. In the case of starch, while not statistically significant, a trend was observed indicating the same inhibitory effect of a reduction in the glycemic response by allulose. Based on the findings of Matsuo and Izumori (2009), it can be concluded that allulose does not induce a glycemic response per se, and also suppresses the glycemic response of other carbohydrates.

Baek et al. (2010) reported the results of a comparative study on the effects of ingesting different types of carbohydrates on glycemic response, the release of insulin, and lipid profiles using as a model diabetic *C57BL/6J* rats. Rats were orally administered 200 mg/kg bw of allulose, glucose, fructose, or water (control), for 28 days. In addition to no adverse effects being observed that were associated with the intervention with the monosaccharide used, they also demonstrated that allulose was capable of maintaining the initial glycemic level between 276 and 305 mg/dL for the entire intervention period, whereas all of the other test groups showed glycemia that was twice as high ($p < 0.05$). Moreover, allulose was demonstrated to be safe, significantly increasing the tolerance to glucose ($p < 0.05$) and even reversing the hepatic concentrations of triglycerides (37.9%) and total cholesterol (62.9%) without any effect on the serum insulin concentration (Baek et al., 2010).

Human studies

Iida et al. (2008) published the results of their study on the effects of ingesting allulose on glycemic and insulinemic response of healthy individuals. In this blind, crossover, and randomized study, eleven men and nine women aged between 20 and 39 years consumed a single dose of four test beverages containing 75 g of maltodextrin and supplemented with 0 g, 2.5 g, 5 g, or 7.5 g of allulose, with minimum intervals of one week between the different forms of intervention. In parallel, eight participants were given 7.5 g of allulose in isolated form to evaluate the effect of consuming the pure monosaccharide on the concentration of plasma insulin and glucose (Iida et al., 2008). Blood samples were collected before initiation of the intervention and also at an interval of 30 minutes, up to 2 hours after the interventions. The results showed that, besides the absence of adverse effects related to the intervention, the independent consumption of the monosaccharide did not influence the glycemic and insulinemic levels of the individuals (Iida et al., 2008).

Another clinical research study was conducted by Hayashi et al. (2010) to investigate the safety and effect of allulose on postprandial blood glucose levels in adult men and women, including borderline diabetic patients. A randomized double-blind, placebo-controlled, crossover experiment of single ingestion was conducted on 26 subjects who consumed 0 or 5 g of allulose in tea with a standard meal. Blood glucose levels at fasting and 30, 60, 90, and 120 min after the meal were compared. The blood glucose level was significantly lower 30 and 60 min after the meal with allulose ($p < 0.01$, $p < 0.05$), and a significant decrease was also shown in the area under the curve ($p < 0.01$). The results suggest that allulose had the effect of suppressing the postprandial blood glucose elevation, mainly in borderline diabetic cases. Another randomized double-blind placebo-controlled parallel-group experiment of long-term ingestion was conducted on 17 normal subjects who ingested 5 g of allulose ($n=8$) or D-glucose ($n=9$) with meals three times a day (total 15 g/day) for 12 continuous weeks. No adverse effects or clinical problems from the continuous ingestion of allulose were reported (Hayashi et al., 2010).

In a double-blind, randomized, multi-center, controlled study that evaluated and tested the effect of single doses of 0 (control), 5.0, or 10 g of allulose, added in a solution containing 75 g of glucose, at glycemia up to 120 minutes in 24 subjects (12 males and 12 females aged 66 ± 1.2 years; BMI 27.0 ± 0.9 kg/m²; diabetes duration 11.3 ± 1.7 years; HbA1c 50.0 ± 1.3 mmol/mol [$6.7 \pm 0.1\%$] with type-2 diabetes (Noronha et al., 2018). The study showed that allulose is able to reduce significantly the plasma glucose iAUC by 8% at 10 g, when compared with the control (717.4 ± 38.3 versus 777.5 ± 39.9 mmol·min/L, $p=0.015$) with a linear dose-response gradient between the reduction in plasma glucose iAUC and dose ($p=0.016$). Allulose also significantly reduced several related secondary and exploratory outcome measures at 5.0 g (plasma glucose absolute mean and total AUC) and at 10 g (plasma glucose absolute mean, absolute and incremental maximum concentration [C_{max}], and total AUC) ($p < 0.0125$). There was no effect of fructose at any dose. Although allulose showed statistically significant reductions in plasma glucose iAUC compared with fructose at both 5.0 g, 10 g, and pooled doses, these reductions were within the prespecified equivalence margins of $\pm 20\%$.

Two unpublished clinical studies were conducted to evaluate the glycemic response of Dolcia Prima® allulose in healthy individuals and diabetics (Kendall et al., 2014-unpublished; Wolever et al., 2014-unpublished).

While the first study evaluated the effects on glycemia in 10 healthy adult individuals, the second study measured the glycemia and insulinemia of 12 healthy adults and 12 patients with type-2 diabetes. In both studies, beverages supplemented with 25 g of Dolcia Prima® allulose, or 25 g of glucose (control) were administered, with the glycemic and/or the insulinemic response measured before and 15, 30, 45, 60, 90, and 120 minutes after the intervention. It was demonstrated that the ingestion of 25 g of the allulose did not cause a glycemic or insulinemic peak above fasting levels in either the healthy or diabetic population (Kendall et al., 2014-unpublished; Wolever et al., 2014-unpublished).

After reviewing the effects of allulose on glycemia and insulinemia, Chung et al. (2012) concluded that the monosaccharide contributed to maintaining appropriate levels of plasma glucose and insulin, characterizing it as a safe and strategic alternative ingredient for substitution of the sugars in the diet of individuals who are at high risk of developing type-2 diabetes.

Safety Summary

Based on the preclinical and clinical safety studies summarized above, the following can be concluded:

- Regulatory authorities have reviewed the safety of allulose and found it to be safe for use in human food. Numerous studies and publications support the safety of allulose, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans.
- A summary of the most relevant studies on allulose ADME, acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, and chronic toxicity in animals along with clinical studies have been summarized and reviewed. The compositional profile of allulose presents no obvious safety concerns. As a result, allulose has been reviewed and approved in several countries for addition to food for human consumption.
- ADME data on allulose are available in both animals and humans, and the data are similar for both.
- Allulose is rapidly absorbed such that large bolus doses are more likely to have an impact on laxation than smaller cumulative doses. As such, clinical studies have demonstrated that the tolerability of allulose is highly dependent on the mode and timeline of ingestion. Individual tolerance develops with continued ingestion over time. Mild GI intolerance is considered to be a physiological response to osmotic loading of no toxicological significance, is generally self-limiting, and not severe or indicative of toxicity per se but is a short-term individual tolerability issue similar to other foods (dried fruit) or food ingredients (fructose), and other sweeteners such as polyols like sorbitol, mannitol, and xylitol.
- No adverse effects attributable to allulose were observed in multiple animal studies; in a 90-day study (2000 mg/kg bw/day) and in a chronic study (approximately 1300 mg/kg bw/day).
- Data are available from a number of human studies in both sexes, healthy individuals, and sensitive subpopulations such as diabetics.
- No effects were observed in multiple human studies, except gastrointestinal intolerance at very high dose levels. Gastrointestinal intolerance is related to the presence of excess indigestible material in the gastrointestinal tract and is

temporary and reversible. It is not unique to allulose; similar effects are observed with other sweeteners, such as polyols like sorbitol, mannitol, and xylitol.

- Allulose can be considered safe for human consumption at up to 63 g/day, when consumed in portions throughout the day as one would typically, based on multiple meals or snacks throughout the day (Han et al., 2018), and up to 28–42 g (0.4–0.6 g/kg/day for a 70 kg individual) can be consumed in one sitting (Han et al., 2018; Iida et al., 2007).
- In summary, the published study data, additional unpublished supporting data, and previous reviews by regulatory authorities (e.g., GRN Nos. 400, 498, 693), support the conclusion that Tate & Lyle’s allulose ingredient is safe for use as a sweetener, at the proposed use levels foods.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered GRAS in accordance with section 201(s) (21 U.S.C. § 321(s)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. Seq.) (“the Act”) is set forth at 21 CFR 170.30, which states:

General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of allulose in selected human food that is the subject of this GRAS determination is GRAS based on scientific procedures. All data relied upon in this GRAS determination are publicly available and generally known, and therefore meet the “general recognition” standard under the Federal Food, Drug, and Cosmetic Act. Unpublished study data are included only as supportive and corroborative of the publicly available data and information.

Safety Determination

The subject of this GRAS determination is the use of allulose as a sweetener in selected foods. Allulose is currently marketed for use in food for human consumption. This GRAS determination supports additional new uses. Regulatory authorities have reviewed the extensive safety database on allulose and found no issues of concern with respect to its use in human food at the proposed use levels. Numerous studies have been conducted and published and unpublished data are available that provide support for the safety of the intended uses of allulose, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults.

Allulose is considered GRAS for use in food for human consumption (GRNs 400, 498, 693) (FDA, 2012, 2014, 2017). One additional GRAS notification is pending (GRN 828). To date, Tate & Lyle's allulose ingredient has been approved for direct use in foods by the U.S. FDA, and regulatory bodies in Mexico, Chile, Columbia, Costa Rica, Singapore, and South Korea.

The safety of orally administered allulose has been characterized extensively in the publicly available preclinical and clinical study literature. The compositional profiles and specifications for both Tate & Lyle's proposed allulose syrup and crystalline products present no obvious safety concerns. Finally, similar allulose products have been reviewed and approved around the world for addition to food.

General Recognition of the Safety of Allulose

The intended use of the allulose ingredient in human food has been determined to be safe through scientific procedures set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination, based on the following:

- Allulose is manufactured from corn, following current cGMP for food (21 CFR § Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food. The allulose ingredient has been characterized appropriately, contains a minimum of 95%–98% allulose (syrup and crystalline forms, respectively), and meets appropriate food-grade specifications.
- There is a body of common knowledge of historical human consumption of allulose from foods containing allulose. Allulose is naturally present in small quantities in many common foods, such as in dried fruits (e.g., figs, raisins, fried dough, brown sugar, and ketchup). The additional intended uses will be in alcoholic beverages, meat/poultry products, grain-based cereal bars, dried cranberries, and presweetened cereal as a sweetener.

- Allulose is currently added to food, and multiple GRAS “no-questions” letters have been issued (GRNs 400, 498, 693) that support the safe use of allulose in foods in which it serves as a sugar replacement/sweetener .
- The proposed uses result in a total population group *per user* 90th percentile intake range of 5.8-8.5 g/day, with the highest overall *per user* 90th percentile intake being in the 19+ age group and the lowest in the 2- to 5-year age group. The population group *per user* 90th percentile intakes normalized for body weight ranged from 0.12 to 0.34 g/kg bw/day, with the highest overall *per user* 90th percentile intake being in the 2- to 5-year age group and the lowest in the 19+ age group.
- Compared to intake assessments in previous GRAS notifications, the addition of allulose to the new food categories represents an intake of approximately 6 – 8.5 g/day by a 90th percentile allulose intake consumer. Given a previously estimated daily intake of approximately 30 g/day (e.g., GRN 693), the cumulative estimated daily intake (CEDI) is approximately 35.8 - 38.5 g/day.
- Allulose can be considered safe for human consumption at up to 63 g/day, when consumed in portions throughout the day as one would typically, based on multiple meals or snacks throughout the day. and up to 28–42 g (0.4 – 0.6 g/kg/day for a 70 kg individual) can be consumed in one.
- No safety/toxicity concerns related to consumption of allulose are evident, beyond that of gastrointestinal intolerance at high bolus doses.
- Regulatory authorities have reviewed the extensive safety study database for allulose and found no issues of concern with respect to its use in human food at the proposed use levels. Numerous studies have been conducted and published in support of the safety of allulose, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults.
- The body of publicly available scientific literature on the consumption and safety of allulose is sufficient to support the safety and GRAS status of the proposed new uses of the allulose ingredient.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called “common knowledge” element of a GRAS determination.

Determination of the safety and GRAS status of the allulose ingredient that is the subject of this self-determination has been made through the deliberations of a GRAS Panel of qualified experts convened by Tate & Lyle and comprised of Michael Carakostas, DVM, Ph.D., Stanley M. Tarka, Jr., Ph.D., F.A.T.S., and Thomas Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the

safety of substances intended to be added to food. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that the allulose ingredient, produced in a manner consistent with cGMP and meeting the specifications described herein, is safe under its intended conditions of use.

The Panel further unanimously concluded that use of the allulose ingredient in these additional specified human foods described herein is GRAS based on scientific procedures, and that other experts qualified to assess the safety of food and food ingredients for human consumption would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit I to this document.

It is also Tate & Lyle's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Tate & Lyle has concluded that the allulose ingredient is GRAS under the intended conditions of use on the basis of scientific procedures; and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Tate & Lyle is not aware of any information that would be inconsistent with a finding that the use of the allulose ingredient in food for human consumption, meeting appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

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Pariza and Johnson Decision Tree

Appendix 4 - Analysis of Safety Based on Pariza/Johnson Decision Tree

Guidelines have been published for the safety assessment of microbial enzyme preparations (Pariza and Johnson, 2001). The guidelines have proven to be a useful tool in safety assessments for the production and use of numerous food enzymes. The safety assessment of a given enzyme preparation is based upon an evaluation of the toxigenic potential of the production organism. The responses below follow the pathway indicated in the decision tree. The outcome of this analysis is that the epimerase enzyme preparation is accepted as safe for its intended use.

1. Is the production strain genetically modified? Yes, go to 2.
2. Is the production strain modified using r DNA techniques? Yes, go to 3a.
3. a. Does the expressed enzyme product which is encoded by the introduced DNA have a history of safe use? This epimerase enzyme is novel but the epimerase enzyme has been used previously to make a food sweetener that was the subject of a GRAS Notification that has been reviewed by FDA (GRN 400); Yes, go to 3c.
- c. Is the test article free of transferable antibiotic resistance gene DNA? No, go to 3d.
- d. Does the resistance gene(s) code for resistance to a drug substances used in the treatment of disease agents in man or animal? Due to its toxicity characteristics, chloramphenicol is not a clinically important antibiotic. No, go to 3e.

- e. Is all other introduced DNA well characterized and free of attributes that would render it unsafe for constructing microorganisms to be used to produce food-grade products? **Yes, go to 4.**
4. Is the introduced DNA randomly integrated into the chromosome? **No, go to 6.**
6. Is the production strain derived from a safe lineage, as previously demonstrated by repeated assessment via this evaluation procedure? **Yes. *E. Coli* K-12 is a well established strain with a history of safe use. Accept.**

APPENDIX B

**COAs and Other
Analytical Data**

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima LS YP19D03774

Manufacture Date May 6, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Off white	Visual inspection
Allulose	% dsb	96.2	>95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.6	<5%	Saccharide distribution – TN67435
pH		4.2	3.0-4.5	pH – TN60710
Dry solids	%	70.8	70% to 78%	DS RIM – TN27501
Total plate count	CFU/10 g	<10	<200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	E. coli – TN 10512L
Salmonella	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	Salmonella – TN 10547
Yeast	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
Mold	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	15.8	<0.10 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Lead	Ppb	5.6	<0.10 ppm	AOAC 993.14

Cadmium	Ppb	<0.005	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Mercury	ppb	<0.005	<0.01 ppm	AOAC 993.14



Shana Bender – Manager Analytical

9-26-19

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	NA

Analytical Data

Sample Number: Dolcia Prima LS YP19G01863

Manufacture Date: April 27, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Colourless to slightly yellow	Visual inspection
Allulose	% dsb	96.34	>95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.87	<5%	Saccharide distribution – TN67434
pH	%	3.9	3.0-4.5	pH – TN60710
Dry solids	%	70.5	70% to 78%	DS RI M – TN27501
Total plate count	CFU/10 g	<10	<200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	<i>E. coli</i> TN 10512L
Salmonella	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	<i>Salmonella</i> – TN 10547
Yeast	CFU/10 g	<10	<10 CFU/10 g	Mold & Yeast – TN10600; TN47010
Mold	CFU/10 g	<10	<10 CFU/10 g	Mold & Yeast – TN10600; TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	11.4	<0.10 ppm	AOAC 993.14; 984.27; 985.01; 2011.14

Lead	Ppb	<5	<0.10 ppm	AOAC 993.14
Cadmium	Ppb	<5	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Mercury	ppb	<5	<0.01 ppm	AOAC 993.14


Shana Bender – Manager Analytical

9-26-19

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	NA

Analytical Data

Sample Number: Dolcia Prima LS YP18D03177

Manufacture Date April 13, 2018

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Colourless to slightly yellow	Visual inspection
Allulose	% dsb	96.3	>95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.4	<5%	Saccharide distribution – TN67435
pH		4.3	3.0-4.5	pH – TN60710
Dry solids	%	71	70% to 78%	DS RI M – TN27501
Total plate count	CFU/10 g	<10	<200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	E. Coli - TN 10512L
Salmonella	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	Salmonella – TN 10547
Yeast	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
Mold	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010

SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	23.8	<0.10 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Lead	Ppb	6	<0.10 ppm	AOAC 993.14
Cadmium	Ppb	<5	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Mercury	ppb	<5	<0.01 ppm	AOAC 993.14

Shana Bender – Manager Analytical

9-26-19
Date

TATE&LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

Product: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima DS LO18J90596

Manufacture Date November 15, 2018

Analysis	Unit	Result	Specification	Methods
Color	n/a	Off white	Off white	Visual inspection
Screen	%	0.1	<5%	
screen	%	7	<10%	
Allulose	% dsb	99.35	>99.1%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.27	<2%	Saccharide distribution – TN67435
moisture	%dsb	0.14	<1.0%	Moisture – TN46040
Ash	% dsb	<0.1%	0.5%	Ash – TN 09580
Total plate count	CFU/10 g	<10	<200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	Enterobacteriaceae/e coli
Salmonella	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	<i>Salmonella</i>
Yeast	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
Mold	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	<5	<0.10 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Lead	Ppb	<5	<0.10 ppm	AOAC 993.14
Cadmium	Ppb	<5	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14

Mercury	ppb	<5	<0.01 ppm	AOAC 993.14
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[Redacted]

9-26-19

Shana Bender – Manager Analytical

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	NA

Analytical Data

Sample Number: Dolcia Prima DS LO19F90351

Manufacture Date: June 3, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Off white	Off white	Visual inspection
Screen	# 10	0.1	<5%	
screen	# 200	3	<10%	
Allulose	% dsb	99.74	>99.1%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.06	<2%	Saccharide distribution – TN67434
moisture	%dsb	0.12	<1.0%	Moisture – TN46040
Ash	% dsb	<0.1%	0.5%	Ash – TN 09580
Total plate count	CFU/10 g	10	<200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	E. Coli TN10512L
Salmonella	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	Salmonella TN 10547
Yeast	CFU/10 g	10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
Mold	CFU/10 g	10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	<5	<0.10 ppm	AOAC 993.14; 984.27; 985.01;

				2011.14
Lead	Ppb	<5	<0.10 ppm	AOAC 993.14
Cadmium	Ppb	<5	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Mercury	ppb	<5	<0.01 ppm	AOAC 993.14

Shana Bender – Manager Analytical

9-26-14

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS

ICD CERTIFICATE OF ANALYSIS

Product: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	NA


Analytical Data

Sample Number: Dolcia Prima DS LO18J90294

Manufacture Date October 3, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Off white	Visual inspection
Screen US#10	%	0.1	<5%	
Screen US #200	%	6.6	<10%	
Allulose	% dsb	99.19	>99.1%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.29	<2%	Saccharide distribution – TN67435
moisture	%dsb	0.1	<1.0%	Moisture – TN46040
Ash	% dsb	<0.1%	0.5%	Ash – TN 09580
Total plate count	CFU/10 g	10	<200 CFU/10 g	Total Plate Count –TN10560
<i>E. Coli.</i>	CFU/10 g	None detected	ISO 21528-1:2004, MSZ ISO 21528-2:2007	<i>E. Coli</i> - TN10512
<i>Salmonella</i>	CFU/ 25 g	Negative	MSZ-EN-ISO 6579:2006	<i>Salmonella</i> TN 10547
Yeast	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010
Mold	CFU/10 g	<10	<10 CFU/10 g	Mold&Yeast – TN10600; TN47010

SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	Ppb	<5	<0.10 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Lead	Ppb	<5	<0.10 ppm	AOAC 993.14
Cadmium	Ppb	<5	<1.0 ppm	AOAC 993.14; 984.27; 985.01; 2011.14
Mercury	ppb	<5	<0.01 ppm	AOAC 993.14


Shana Bender – Manager Analytical

9-26-19
Date

APPENDIX C

Stability Testing Data

Shelf Life Stability DOLCIA PRIMA® LS Allulose Syrup DOLCIA PRIMA® DS Crystalline Allulose

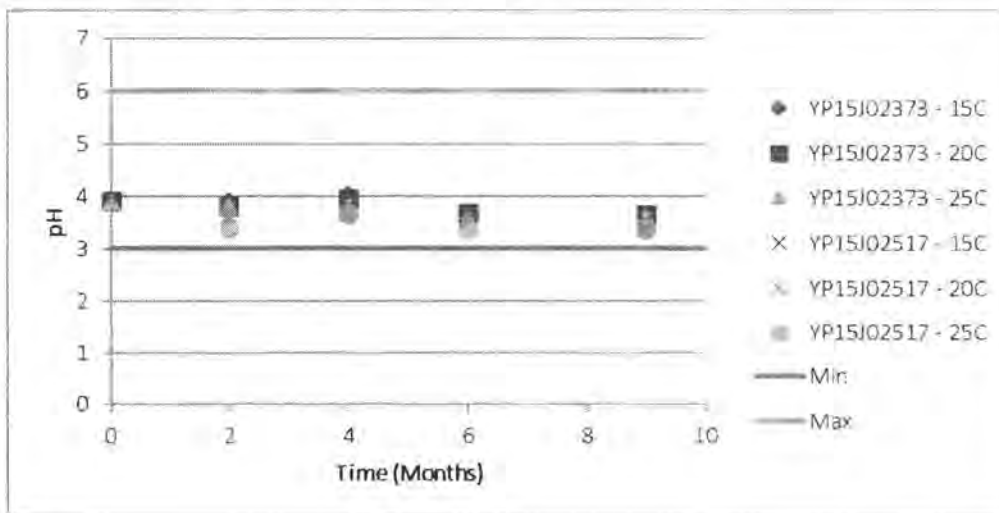
Based on the studies summarized below, the shelf life of DOLCIA PRIMA® LS Allulose Syrup is shown to be at least 9 months when stored at the recommended storage temperature, i.e. 25° C. In this study, the test samples were stored in tightly sealed glass jars in a dark chamber at ambient humidity.

The shelf life of DOLCIA PRIMA® DS Crystalline Allulose is shown to be at least 26 months when stored at the recommended storage conditions of 25° C, <50% RH. In this study, the samples were heat sealed in pouches made from the plastic bag liner which provides a moisture barrier in the DOLCIA PRIMA® DS bag. These pouches were stored in a dark chamber with humidity controlled to <50% RH.

A. pH Stability

The pH of DOLCIA PRIMA® Allulose Syrup decreased gradually throughout shelf-life study at all temperatures tested (Figure 1). The material remained within specification for duration of the 9 month period at 25°C and below.

Figure 1. pH Stability of DOLCIA PRIMA® LS Allulose Syrup



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B. Color Stability of DOLCIA PRIMA® LS Allulose Syrup

One of the key factors that define the end of shelf life for a syrup is color development. As shown in Figure 2, the rate of color development is strongly influenced by temperature. No color generation was seen at 4°C, and only a mild color increase was seen at 25°C over 6 months. Based on color, the syrup should be kept at 25°C for any storage beyond 1 month. Extended storage at these recommended conditions is shown in Figure 3.

Figure 2. Color Stability of DOLCIA PRIMA® Allulose Syrup 4°C – 35°C

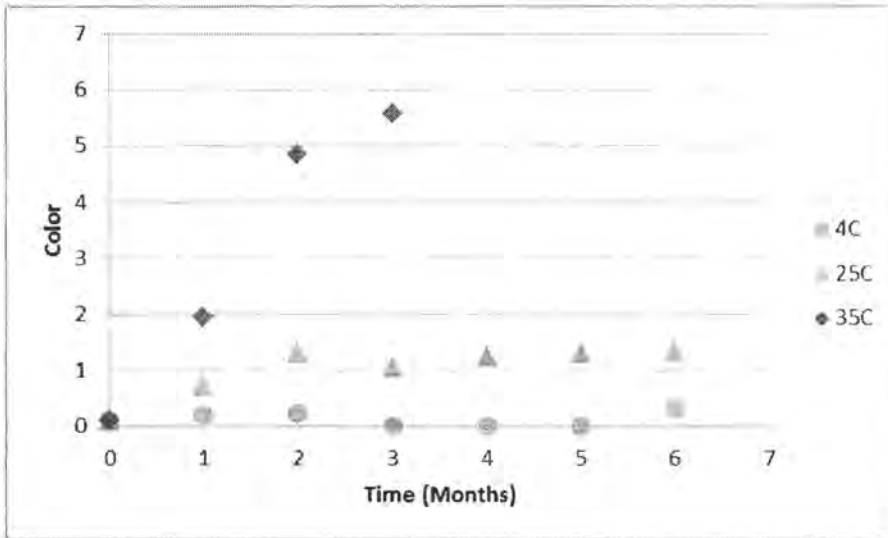
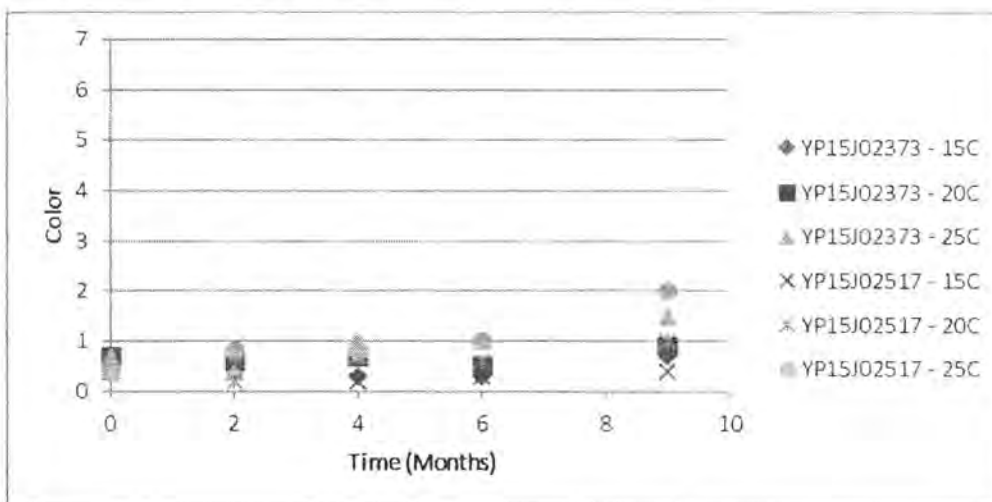


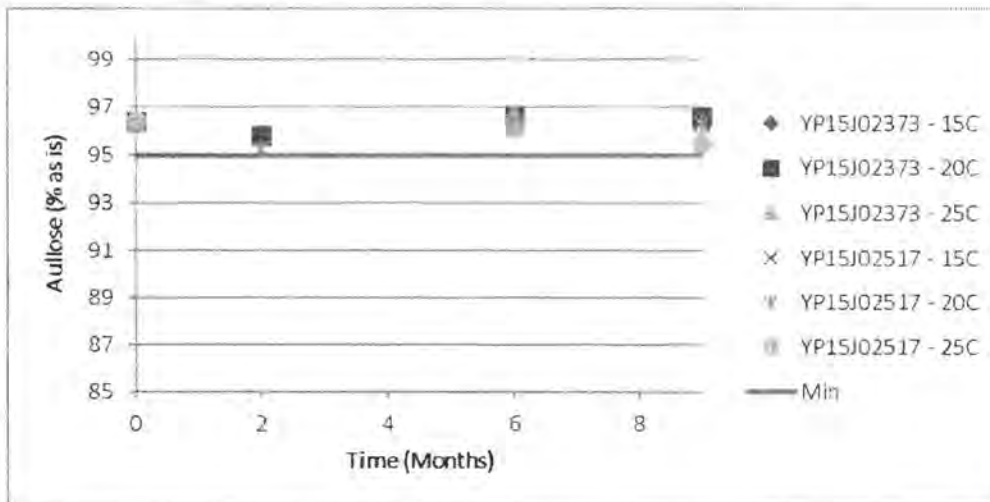
Figure 3. Color Stability of DOLCIA PRIMA® LS Allulose Syrup at 15°C, 20°C, and 25°C



C. Composition Stability of DOLCIA PRIMA® LS Allulose Syrup

The main component of DOLCIA PRIMA® LS Allulose Syrup is allulose. The allulose did not change significantly during the 9 month storage (Figure 4).

Figure 4. Composition Stability of DOLCIA PRIMA® Allulose Syrup



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D. Microbial Stability of DOLCIA PRIMA® Allulose Syrup

The DOLCIA PRIMA® Allulose Syrup tested has a water activity of approximately 0.66 which is very similar to other corn syrups and HFCS products. Microbial growth is not supported in these products due to the low water activity as demonstrated in Table 1. In addition, Tate & Lyle has conducted a challenge study on DOLCIA PRIMA® Allulose Syrup with Salmonella and E. Coli which showed that these microorganisms died off after 1 day at room temperature.

Table 1. Microbial Stability of DOLCIA PRIMA® Allulose Syrup

Temp (°C)	Month	E Coli	Salmonella	Total Plate Count	Mold	Yeast
4	0	NEGATIVE	NEGATIVE	<10	<10	<10
	3	NEGATIVE	NEGATIVE	20	<10	<10
	6	NEGATIVE	NEGATIVE	<10	<10	<10
	9	NEGATIVE	NEGATIVE	<10	<10	<10
25	0	NEGATIVE	NEGATIVE	<10	<10	<10
	3	NEGATIVE	NEGATIVE	<10	<10	<10
	6	NEGATIVE	NEGATIVE	<10	<10	<10
	9	NEGATIVE	NEGATIVE	<10	<10	<10
35	0	NEGATIVE	NEGATIVE	<10	<10	<10
	3	NEGATIVE	NEGATIVE	20	<10	<10
	6	NEGATIVE	NEGATIVE	<10	<10	<10

E. Stability of DOLCIA PRIMA® DS Crystalline Allulose

Stability studies on DOLCIA PRIMA® DS Crystalline Allulose are currently underway. Allulose composition and moisture are unchanged after 30 months (2.5 years) when stored in original packaging at the recommended storage conditions of 77 degrees Fahrenheit (25°C) or lower and 50% or less relative humidity. This is similar to other crystalline saccharides such as crystalline fructose or crystalline glucose. DOLCIA PRIMA® DS Crystalline Allulose is an anhydrous crystalline product with moisture <0.5% and therefore does not support microbial growth.

Figure 5. Composition Stability of DOLCIA PRIMA® DS Crystalline Allulose at 25°C

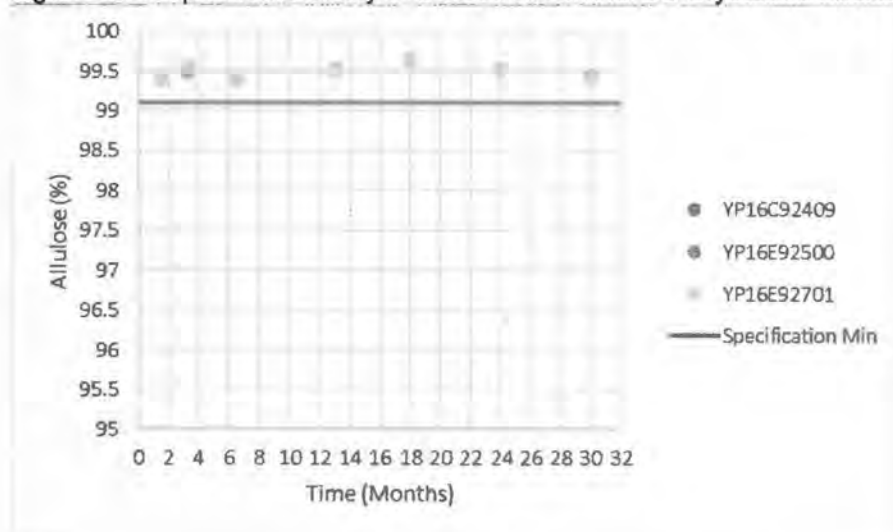
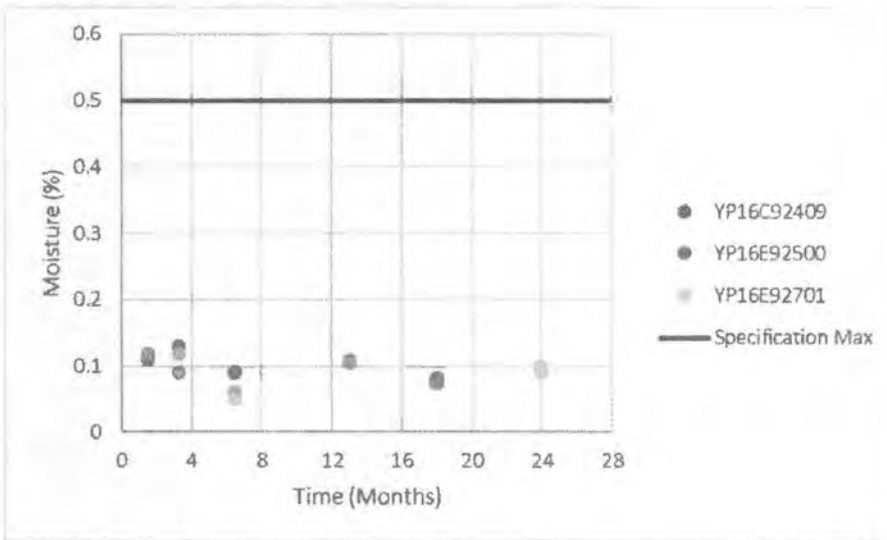


Figure 6. Moisture uptake of DOLCIA PRIMA® DS Crystalline Allulose at 25°C, <50% RH

TATE & LYLE



Brian Pohrte, Research Chemist

The information contained in this bulletin should not be construed as recommending the use of our product in violation of any patent, or as warranties (expressed or implied) of its fitness for any particular purpose. Prospective purchasers are invited to conduct their own tests, studies and regulatory review to determine the fitness of Tate & Lyle products for their particular purposes product claims or specific applications.

APPENDIX D

Intake Assessment Report

Estimated Daily Intake of Allulose

DECEMBER 4, 2019

ToxStrategies

Innovative solutions
Sound science

Estimated Daily Intake of Allulose

DECEMBER 4, 2019

PREPARED FOR:

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PREPARED BY:

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List of Acronyms and Abbreviations

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
EDI	estimated daily intake
EPA	Environmental Protection Agency
g/day	grams per day
g/kg BW/day	grams per kilogram body weight per day
NHANES	National Health and Nutrition Examination Survey
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

1.0 Executive Summary

ToxStrategies, Inc. (ToxStrategies) has conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient allulose based on its intended use in foods. This assessment included several proposed food categories for use of allulose: alcoholic beverages (malt beverages, wine coolers, and pre-mixed cocktails); processed meat products (jerky; glazed ham, and formed deli meats); condiments (ketchup and barbecue sauce); cereal bars; dried cranberries; and pre-sweetened breakfast cereal. After analyzing dietary survey data from the National Health and Nutrition Examination Survey (NHANES), the *per user* mean and 90th percentile estimated daily intake (EDI) of allulose for the US population ages 2 and over were determined to be 3.75 and 8.25 g/day (0.0656 and 0.154 g/kg body weight/day), respectively. The *per capita* mean and 90th percentile EDI of allulose for the US population ages 2 and over were determined to be 2.71 and 7.05 g/day (0.0474 and 0.127 g/kg body weight/day), respectively.

2.0 Data

To calculate the EDI of allulose, information about its proposed uses in foods was combined with up-to-date, publicly available dietary intake survey data. Data sources are described in the following sections.

2.1 Proposed Uses and Use Levels of Allulose

Tate & Lyle proposes to use allulose in various food categories according to Table 1.

Table 1. Proposed uses and use levels of allulose

Food Category	Food Subcategory	Maximum Proposed Use Level (% by mass)
Alcoholic beverages	Malt beverages	3.5%
	Wine coolers	3.5%
	Premixed cocktails	3.5%
Processed meat products	Jerky	15%
	Glazed ham	5%
	Formed deli meats	2%
Condiments	Ketchup	10%
	Barbecue sauce	10%
Cereal bars		25%
Dried cranberries		25%
Pre-sweetened breakfast cereal		10%

2.2 Dietary Survey Data

Dietary survey data was obtained from What We Eat in America (WWEIA), the dietary interview portion of the National Health and Nutrition Examination Survey (NHANES). NHANES is carried out in two-year cycles (biennials) by the Centers for Disease Control and Prevention (CDC) in order to characterize the general health and nutritional status of children and adults across the US. The dietary intake survey portion of NHANES is a joint effort between CDC and the US Department of Agriculture (USDA). All NHANES biennials for which dietary intake data was available were included in this analysis (2003-2004, 2005-2006, 2007-2008, 2009-2010, 2011-2012, 2013-2014, and 2015-2016).

The first day of the WWEIA dietary questionnaire was administered in person, in conjunction with the participants' interviews and examinations for the other NHANES lifestyle and laboratory assessments. The second day of the survey was collected via a phone interview at some point three to ten days after the first survey day. Data collected during the dietary

interview includes foods as consumed by the participant, encoded by a food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA; only reliable respondents who also provided body-weight data were considered in this analysis.

3.0 Methods

To estimate the intake of allulose from its proposed uses, ToxStrategies performed the following steps:

- Step 1: Identified foods and their components to which allulose may be applied
- Step 2: Calculated individual intake of allulose for individual survey participants
- Step 3: Calculated population statistics estimating intake of allulose

Details of each step are provided in the following sections.

3.1 Identification of Foods and Their Components to Which Allulose May Be Applied

To identify foods that are proposed to contain allulose, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food code descriptions from WWEIA were manually examined and flagged if they could be considered members of one or more of the food categories specified in Table 1. Food codes retained for further analysis are listed in the appendix.

3.2 Calculation of Individual Intake of Allulose for Individual Survey Participants

Only those respondents designated as reliable were included in this assessment. Both days of the NHANES WWEIA dietary interviews from each biennial were analyzed. Participants' consumption of the allulose was averaged over the two response days, *i.e.* (Day1 consumption + Day2 consumption)/2. Consumption of allulose was calculated using the grams of the relevant food consumed as reported in NHANES, multiplied by the maximum proposed use level of allulose in that food. For example, for the food "25210210 Frankfurter (beef)", the maximum proposed use level was 2% (in category "Processed meat and poultry products – Formed deli meats"). Thus, a survey participant who consumed 100g of this food would consume 2g of allulose.

3.3 Calculation of Population Statistics Describing Allulose Estimated Daily Intake

All NHANES biennials for which dietary intake data was available were included in this analysis (2003-2004, 2005-2006, 2007-2008, 2009-2010, 2011-2012, 2013-2014, and 2015-2016). The dietary and sample weighting data from the two biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined dataset, we estimated survey-design-weighted descriptive statistics for the population consumption per day. Population statistics were estimated using the "survey" package version 3.36 (Lumley, 2004) in the R (version 3.6.1) environment for statistical computing (R Core Team, 2019) using the appropriate adjustment to sampling weights for combining biennials, then incorporating survey

sampling units and strata from the survey design to ensure that sub-populations and areas were correctly represented. Descriptive statistics (mean, 90th percentile) were calculated for the subset of consumers of allulose and for the entire population; these were broken down by age range and body weight adjustment. Values were provided by individual food category and for total consumption of foods in all food categories.

4.0 Results

Tables 2 and 3 below, respectively, present the EDI for allulose in grams per day and grams per kilogram body weight per day for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older. The “number of users” refers to the number of survey participants in a given age group who consumed a food item in given food category. The “percent users” is the percentage of allulose users out of the total number of reliable survey participants (users and non-users) belonging to a given age group. Intake is provided for each of the food categories and subcategories listed in Table 1. “Total” values include users who consumed foods in any of the proposed food categories. **Note that the “Total” values are not simple sums of the values listed above them.**

Table 2. Estimated daily intake for allulose (g/day)

Food Category	Number of Users	Percent Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Alcoholic beverages	508	1.01%	7.58	15.2	0.109	0.00
<i>Malt beverages</i>	75	0.15%	11.1	18.9	0.0246	0.00
<i>Wine coolers</i>	150	0.30%	8.98	17.7	0.0284	0.00
<i>Pre-mixed cocktails</i>	290	0.58%	6.10	12.1	0.0561	0.00
Processed meat products	19281	38.46%	1.18	2.28	0.455	1.40
<i>Jerky</i>	10	0.02%	5.20	11.1	1.03E-03	0.00
<i>Glazed ham</i>	1858	3.71%	1.98	4.25	0.0783	0.00
<i>Formed deli meats</i>	18084	36.07%	1.04	2.04	0.375	1.14
Condiments	13184	26.30%	1.34	3.00	0.340	1.00
<i>Ketchup</i>	11615	23.17%	1.24	3.00	0.268	0.750
<i>Barbecue sauce</i>	2274	4.54%	1.45	3.13	0.0711	0.00
Cereal bars	2331	4.65%	6.40	10.8	0.401	0.00
Dried cranberries	485	0.97%	2.88	6.88	0.0428	0.00
Pre-sweetened breakfast cereal	20205	40.30%	3.60	6.76	1.36	4.50
Total*	36278	72.37%	3.75	8.25	2.71	7.05

Food Category	Number of Users	Percent Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2-5						
Alcoholic beverages	0	0%	—	—	—	—
<i>Malt beverages</i>	0	0%	—	—	—	—
<i>Wine coolers</i>	0	0%	—	—	—	—
<i>Pre-mixed cocktails</i>	0	0%	—	—	—	—
Processed meat products	2091	45.13%	0.889	1.71	0.410	1.14
<i>Jerky</i>	1	0.02%	12.8	—	0.0158	0.00
<i>Glazed ham</i>	114	2.46%	1.60	3.73	0.0431	0.00
<i>Formed deli meats</i>	2031	43.84%	0.789	1.63	0.351	1.12
Condiments	1607	34.69%	0.949	2.25	0.330	0.938
<i>Ketchup</i>	1517	32.74%	0.927	2.19	0.306	0.875
<i>Barbecue sauce</i>	170	3.67%	0.753	1.60	0.235	0.00
Cereal bars	202	4.36%	4.38	7.00	0.273	0.00
Dried cranberries	24	0.52%	3.65	8.02	0.0326	0.00
Pre-sweetened breakfast cereal	3150	67.99%	2.26	4.30	1.49	3.66
Total*	4081	88.09%	2.87	5.80	2.53	5.51
US Population, Ages 6-18						
Alcoholic beverages	19	0.13%	10.2	18.8	0.0120	0.00
<i>Malt beverages</i>	4	0.03%	10.5	16.9	1.45E-03	0.00
<i>Wine coolers</i>	8	0.06%	13.6	19.6	8.51E-03	0.00
<i>Pre-mixed cocktails</i>	7	0.05%	4.88	5.84	2.01E-03	0.00
Processed meat products	6066	42.08%	1.09	2.08	0.468	1.40
<i>Jerky</i>	1	0.01%	0.589	—	0.0245	0.00
<i>Glazed ham</i>	431	2.99%	1.86	3.96	0.0550	0.00
<i>Formed deli meats</i>	5808	40.29%	1.00	1.95	0.413	1.14
Condiments	5283	36.65%	1.39	3.13	0.505	1.50
<i>Ketchup</i>	4750	32.95%	1.30	3.00	0.421	1.28
<i>Barbecue sauce</i>	859	5.96%	1.40	3.13	0.0838	0.00
Cereal bars	734	5.09%	5.58	10.3	0.368	0.00
Dried cranberries	39	0.27%	4.49	11.5	0.0156	0.00
Pre-sweetened breakfast cereal	7520	52.17%	3.52	6.55	1.83	5.13
Total*	11847	82.19%	3.88	8.21	3.20	7.57
US Population, Ages 19+						

Food Category	Number of Users	Percent Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90th Percentile	Mean	90th Percentile
Alcoholic beverages	489	1.57%	7.54	15.2	0.141	0.00
<i>Malt beverages</i>	71	0.23%	11.1	18.9	0.0320	0.00
<i>Wine coolers</i>	142	0.46%	8.80	16.8	0.0352	0.00
<i>Pre-mixed cocktails</i>	283	0.91%	6.11	12.2	0.0733	0.00
Processed meat products	11124	35.79%	1.23	2.51	0.455	1.40
<i>Jerky</i>	8	0.03%	1.35	3.10	2.20E-04	0.00
<i>Glazed ham</i>	1313	4.22%	2.02	4.25	0.0866	0.00
<i>Formed deli meats</i>	10245	32.96%	1.08	2.24	0.368	1.14
Condiments	6294	20.25%	1.36	3.00	0.300	0.782
<i>Ketchup</i>	5348	17.20%	1.25	3.00	0.229	0.750
<i>Barbecue sauce</i>	1245	4.01%	1.50	3.13	0.0715	0.00
Cereal bars	1395	4.49%	6.76	12.3	0.418	0.00
Dried cranberries	422	1.36%	2.78	6.77	0.0501	0.00
Pre-sweetened breakfast cereal	9535	30.67%	3.84	7.23	1.24	4.38
Total*	20350	65.47%	3.80	8.50	2.60	7.05

* Total values reflect intake from foods in any of the proposed food categories.

Table 3. Estimated daily intake for allulose (g/kg BW/day)

Food Category	Number of Users	Percent Users	EDI per User (g/kg/day)		EDI per Capita (g/kg/day)	
			Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+						
Alcoholic beverages	508	1.01%	0.0994	0.207	1.43E-03	0.00
<i>Malt beverages</i>	75	0.15%	0.134	0.252	2.97E-04	0.00
<i>Wine coolers</i>	150	0.30%	0.118	0.242	3.72E-04	0.00
<i>Pre-mixed cocktails</i>	290	0.58%	0.0827	0.159	7.61E-04	0.00
Processed meat products	19281	38.46%	0.0195	0.0413	7.54E-03	0.0227
<i>Jerky</i>	10	0.02%	0.233	0.490	4.64E-05	0.00
<i>Glazed ham</i>	1858	3.71%	0.0288	0.0617	1.14E-03	0.00
<i>Formed deli meats</i>	18084	36.07%	0.0176	0.0368	6.36E-03	0.0196
Condiments	13184	26.30%	0.0233	0.0523	5.90E-03	0.0169
<i>Ketchup</i>	11615	23.17%	0.0224	0.0500	4.86E-03	0.0131
<i>Barbecue sauce</i>	2274	4.54%	0.0213	0.0487	1.05E-03	0.00
Cereal bars	2331	4.65%	0.108	0.216	6.74E-03	0.00
Dried cranberries	485	0.97%	0.0472	0.102	7.01E-04	0.00
Pre-sweetened breakfast cereal	20205	40.30%	0.0663	0.136	0.0250	0.0796
Total*	36278	72.37%	0.0656	0.154	0.0474	0.127
US Population, Ages 2-5						
Alcoholic beverages	0	0%	—	—	—	—
<i>Malt beverages</i>	0	0%	—	—	—	—
<i>Wine coolers</i>	0	0%	—	—	—	—
<i>Pre-mixed cocktails</i>	0	0%	—	—	—	—
Processed meat products	2091	45.13%	0.0519	0.102	0.0239	0.0693
<i>Jerky</i>	1	0.02%	0.651		8.08E-04	0.00
<i>Glazed ham</i>	114	2.46%	0.0904	0.214	2.44E-03	0.00
<i>Formed deli meats</i>	2031	43.84%	0.0465	0.0927	0.0207	0.0632
Condiments	1607	34.69%	0.0535	0.121	0.0186	0.0556
<i>Ketchup</i>	1517	32.74%	0.0523	0.118	0.0173	0.0521
<i>Barbecue sauce</i>	170	3.67%	0.0422	0.0969	1.32E-03	0.00
Cereal bars	202	4.36%	0.268	0.431	0.0167	0.00
Dried cranberries	24	0.52%	0.225	0.616	2.01E-03	0.00
Pre-sweetened breakfast cereal	3150	67.99%	0.134	0.253	0.0881	0.220

Food Category	Number of Users	Percent Users	EDI per User (g/kg/day)		EDI per Capita (g/kg/day)	
			Mean	90th Percentile	Mean	90th Percentile
Total*	4081	88.09%	0.169	0.338	0.149	0.321
US Population, Ages 6-18						
Alcoholic beverages	19	0.13%	0.155	0.287	1.83E-04	0.00
<i>Malt beverages</i>	4	0.03%	0.171	0.268	2.38E-05	0.00
<i>Wine coolers</i>	8	0.06%	0.214	0.298	1.34E-04	0.00
<i>Pre-mixed cocktails</i>	7	0.05%	0.0610	0.0785	2.51E-05	0.00
Processed meat products	6066	42.08%	0.0250	0.0507	0.0108	0.0333
<i>Jerky</i>	1	0.01%	0.0261	—	1.08E-06	0.00
<i>Glazed ham</i>	431	2.99%	0.0383	0.0825	1.13E-03	0.00
<i>Formed deli meats</i>	5808	40.29%	0.0234	0.0475	9.62E-03	0.0302
Condiments	5283	36.65%	0.0317	0.0704	0.0115	0.0342
<i>Ketchup</i>	4750	32.95%	0.0302	0.0674	9.79E-03	0.0287
<i>Barbecue sauce</i>	859	5.96%	0.0285	0.0617	1.70E-03	0.00
Cereal bars	734	5.09%	0.139	0.274	9.18E-03	0.00
Dried cranberries	39	0.27%	0.114	0.250	3.98E-04	0.00
Pre-sweetened breakfast cereal	7520	52.17%	0.0840	0.161	0.0438	0.126
Total*	11847	82.19%	0.0919	0.201	0.0758	0.185
US Population, Ages 19+						
Alcoholic beverages	489	1.57%	0.0986	0.201	1.84E-03	0.00
<i>Malt beverages</i>	71	0.23%	0.133	0.251	3.86E-04	0.00
<i>Wine coolers</i>	142	0.46%	0.114	0.235	4.57E-04	0.00
<i>Pre-mixed cocktails</i>	283	0.91%	0.0829	0.159	9.95E-04	0.00
Processed meat products	11124	35.79%	0.0150	0.0301	5.59E-03	0.0175
<i>Jerky</i>	8	0.03%	0.0179	0.0292	2.91E-06	0.00
<i>Glazed ham</i>	1313	4.22%	0.0244	0.0515	1.05E-03	0.00
<i>Formed deli meats</i>	10245	32.96%	0.0132	0.0263	4.53E-03	0.0151
Condiments	6294	20.25%	0.0165	0.0366	3.63E-03	0.0113
<i>Ketchup</i>	5348	17.20%	0.0151	0.0341	2.76E-03	8.66E-03
<i>Barbecue sauce</i>	1245	4.01%	0.0182	0.0404	8.68E-04	0.00
Cereal bars	1395	4.49%	0.0879	0.165	5.43E-03	0.00
Dried cranberries	422	1.36%	0.0378	0.0848	6.82E-04	0.00
Pre-sweetened breakfast cereal	9535	30.67%	0.0494	0.0941	0.0159	0.0565
Total*	20350	65.47%	0.0483	0.107	0.0331	0.0886

* Total values reflect intake from foods in any of the proposed food categories.

5.0 References

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Appendix: List of Food Codes

Please see attached Excel document "Appendix A.xlsx"

Food code and description appear in which NHANES biennials? (1 = appears in the corresponding biennial; 0 = does not appear)

Food code	Description	NHANES 2003-2004	NHANES 2005-2006	NHANES 2007-2008	NHANES 2009-2010	NHANES 2011-2012	NHANES 2013-2014	NHANES 2015-2016	Category
22002800	Pork jerky	1	1	1	1	1	1	1	1 Jerky
22311000	Ham, smoked or cured, cooked, NS as to fat eaten	1	1	1	1	1	1	1	0 Glazed_Ham
22311000	Ham, smoked or cured, cooked, NS as to fat eaten	0	0	0	0	0	0	0	1 Glazed_Ham
22311010	Ham, smoked or cured, cooked, lean and fat eaten	1	1	1	1	1	1	1	0 Glazed_Ham
22311010	Ham, smoked or cured, cooked, lean and fat eaten	0	0	0	0	0	0	0	1 Glazed_Ham
22311020	Ham, smoked or cured, cooked, lean only eaten	1	1	1	1	1	1	1	0 Glazed_Ham
22311020	Ham, smoked or cured, cooked, lean only eaten	0	0	0	0	0	0	0	1 Glazed_Ham
22311200	Ham, smoked or cured, low sodium, cooked, NS as to fat eaten	1	1	1	1	1	1	0	0 Glazed_Ham
22311210	Ham, smoked or cured, low sodium, cooked, lean and fat eaten	1	1	1	1	1	1	0	0 Glazed_Ham
22311220	Ham, smoked or cured, eaten	1	1	1	1	1	1	0	0 Glazed_Ham
22311500	Ham, smoked or cured, canned, NS as to fat eaten	1	1	1	1	1	1	1	1 Glazed_Ham
22311510	Ham, smoked or cured, canned, lean and fat eaten	1	1	1	1	1	1	1	0 Glazed_Ham
22311510	Ham, smoked or cured, canned, lean and fat eaten	0	0	0	0	0	0	0	1 Glazed_Ham
22311520	Ham, smoked or cured, canned, lean only eaten	1	1	1	1	1	1	1	1 Glazed_Ham
25210110	Frankfurter, wiener, or hot dog, NFS	1	1	1	1	1	1	1	0 Formed_Deli_Meats
25210110	Frankfurter, wiener, or hot dog, NFS	0	0	0	0	0	0	0	1 Formed_Deli_Meats
25210120	Frankfurter or hot dog, breaded, baked	1	1	1	1	0	0	0	0 Formed_Deli_Meats
25210150	Frankfurter or hot dog, cheese-filled	1	1	1	1	1	1	1	1 Formed_Deli_Meats
25210160	Frankfurter or hot dog, bacon and cheese-filled	1	1	1	1	0	0	0	0 Formed_Deli_Meats
25210170	Frankfurter or hot dog, chili- filled	1	1	1	1	0	0	0	0 Formed_Deli_Meats
25210210	Frankfurter or hot dog, beef	1	1	1	1	1	1	1	1 Formed_Deli_Meats
25210220	Frankfurter or hot dog, beef and pork	1	1	1	1	1	1	1	0 Formed_Deli_Meats
25210220	Frankfurter or hot dog, beef and pork	0	0	0	0	0	0	0	1 Formed_Deli_Meats
25210230	Frankfurter or hot dog, beef and pork, lowfat	1	1	1	1	0	0	0	0 Formed_Deli_Meats
25210240	Frankfurter or hot dog, beef and pork, reduced fat or light	0	0	0	0	1	1	1	0 Formed_Deli_Meats
25210240	Frankfurter or hot dog, beef and pork, reduced fat or light	0	0	0	0	0	0	0	1 Formed_Deli_Meats
25210250	Frankfurter or hot dog, meat and poultry, fat free	1	1	1	1	1	1	1	0 Formed_Deli_Meats
25210250	Frankfurter or hot dog, meat and poultry, fat free	0	0	0	0	0	0	0	1 Formed_Deli_Meats
25210280	Frankfurter or hot dog, meat and poultry	1	1	1	1	1	1	1	0 Formed_Deli_Meats
25210280	Frankfurter or hot dog, meat and poultry	0	0	0	0	0	0	0	1 Formed_Deli_Meats
25210290	Frankfurter or hot dog, meat and poultry, reduced fat or light	0	0	0	0	1	1	1	0 Formed_Deli_Meats

25210290	Frankfurter or hot dog, meat and poultry, reduced fat or light	0	0	0	0	0	0	1	Formed_Deli_Meats
25210310	Frankfurter or hot dog, chicken	1	1	1	1	1	1	1	Formed_Deli_Meats
25210410	Frankfurter or hot dog, turkey	1	1	1	1	1	1	1	Formed_Deli_Meats
25210510	Frankfurter or hot dog, low salt	1	1	1	1	0	0	0	Formed_Deli_Meats
25210610	Frankfurter or hot dog, beef, lowfat	1	1	1	1	0	0	0	Formed_Deli_Meats
25210620	Frankfurter or hot dog, beef, reduced fat or light	0	0	0	0	1	1	1	Formed_Deli_Meats
25210700	Frankfurter or hot dog, meat & poultry, lowfat	1	1	1	1	0	0	0	Formed_Deli_Meats
25210750	Frankfurter or hot dog, reduced fat or light, NFS	0	0	0	0	1	1	1	Formed_Deli_Meats
25220010	Cold cut, NFS	1	1	1	1	1	1	0	Formed_Deli_Meats
25220100	Beef sausage, NFS	1	1	1	1	0	0	0	Formed_Deli_Meats
25220105	Beef sausage	0	0	0	0	1	1	1	Formed_Deli_Meats
25220106	Beef sausage, reduced fat	0	0	0	0	1	1	1	Formed_Deli_Meats
25220108	Beef sausage, reduced sodium	0	0	0	0	0	1	1	Formed_Deli_Meats
25220110	Beef sausage, brown and serve, links, cooked	1	1	1	1	0	0	0	Formed_Deli_Meats
25220120	Beef sausage, smoked, stick	1	1	1	1	0	0	0	Jerky
25220130	Beef sausage, smoked	1	1	1	1	0	0	0	Formed_Deli_Meats
25220140	Beef sausage, fresh, bulk, patty or link, cooked	1	1	1	1	0	0	0	Formed_Deli_Meats
25220150	Beef sausage with cheese, smoked	1	1	1	1	0	0	0	Formed_Deli_Meats
25220150	Beef sausage with cheese	0	0	0	0	1	1	1	Formed_Deli_Meats
25220390	Bologna, beef, lowfat	1	1	1	1	1	1	0	Formed_Deli_Meats
25220400	Bologna, pork and beef	1	1	1	1	1	1	0	Formed_Deli_Meats
25220410	Bologna, NFS	1	1	1	1	1	1	1	Formed_Deli_Meats
25220420	Bologna, Lebanon	1	1	1	1	1	1	0	Formed_Deli_Meats
25220425	Bologna, made from any kind of meat, reduced fat	0	0	0	0	0	0	1	Formed_Deli_Meats
25220430	Bologna, beef	1	1	1	1	1	1	0	Formed_Deli_Meats
25220435	Bologna, made from any kind of meat, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25220440	Bologna, turkey	1	1	1	1	1	1	0	Formed_Deli_Meats
25220445	Bologna, made from any kind of meat, reduced fat and reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25220450	Bologna ring, smoked	1	1	1	1	1	1	0	Formed_Deli_Meats
25220460	Bologna, pork	1	1	1	1	1	1	0	Formed_Deli_Meats
25220470	Bologna, beef, lower sodium	1	1	1	1	1	1	0	Formed_Deli_Meats
25220480	Bologna, chicken, beef, and pork	1	1	1	1	1	1	0	Formed_Deli_Meats
25220490	Bologna, with cheese	1	1	1	1	1	1	0	Formed_Deli_Meats
25220500	Bologna, beef and pork, lowfat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230110	Luncheon meat, NFS	1	1	1	1	1	1	1	Formed_Deli_Meats
25230210	Ham, prepackaged or deli, luncheon meat	0	0	0	0	0	0	1	Formed_Deli_Meats
25230210	Ham, sliced, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230220	Ham, prepackaged or deli, luncheon meat, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25230220	Ham, sliced, low salt, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230230	Ham, sliced, extra lean, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230235	Ham, sliced, extra lean, lower sodium, prepackaged or deli, luncheon meat	0	0	0	0	1	1	0	Formed_Deli_Meats

25230310	Chicken or turkey loaf, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230320	Chicken, prepackaged or deli, luncheon meat	0	0	0	0	0	0	1	Formed_Deli_Meats
25230340	Chicken, prepackaged or deli, luncheon meat, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25230410	Ham loaf, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230420	Ham luncheon meat, loaf type	0	0	0	0	0	0	1	Formed_Deli_Meats
25230430	Ham and cheese loaf	1	1	1	1	1	1	0	Formed_Deli_Meats
25230450	Honey loaf	1	1	1	1	1	1	0	Formed_Deli_Meats
25230510	Ham, luncheon meat, chopped, minced, pressed, spiced, not canned	1	1	1	1	1	1	0	Formed_Deli_Meats
25230520	Ham, luncheon meat, chopped, minced, pressed, spiced, lowfat, not canned	1	1	1	1	1	1	0	Formed_Deli_Meats
25230530	Ham and pork, canned luncheon meat, chopped, minced, pressed, spiced	0	0	0	0	0	0	1	Formed_Deli_Meats
25230530	Ham and pork, luncheon meat, chopped, minced, pressed, spiced, canned	1	1	1	1	1	1	0	Formed_Deli_Meats
25230540	Ham, pork and chicken, luncheon meat, chopped, minced, pressed, spiced, canned	1	1	1	1	1	1	0	Formed_Deli_Meats
25230540	Ham, pork and chicken, canned luncheon meat, chopped, minced, pressed, spiced, reduced fat and reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25230550	Ham, pork, and chicken, luncheon meat, chopped, minced, pressed, spiced, canned, reduced sodium	1	1	1	1	1	1	0	Formed_Deli_Meats
25230550	Ham, pork, and chicken, canned luncheon meat, chopped, minced, pressed, spiced, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25230610	Luncheon loaf (olive, pickle, or pimiento)	1	1	1	1	1	1	0	Formed_Deli_Meats
25230610	Luncheon meat, loaf type	0	0	0	0	0	0	1	Formed_Deli_Meats
25230710	Sandwich loaf, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230780	Turkey, prepackaged or deli, luncheon meat	0	0	0	0	0	0	1	Formed_Deli_Meats
25230785	Turkey, prepackaged or deli, luncheon meat, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats
25230790	Turkey ham, sliced, extra lean, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230800	Turkey ham	1	1	1	1	1	1	0	Formed_Deli_Meats
25230800	Turkey ham, prepackaged or deli, luncheon meat	0	0	0	0	0	0	1	Formed_Deli_Meats
25230900	Turkey or chicken breast, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25230905	Turkey or chicken breast, low salt, prepackaged or deli, luncheon meat	0	0	1	1	1	1	0	Formed_Deli_Meats
25231110	Beef, prepackaged or deli, luncheon meat	0	0	0	0	0	0	1	Formed_Deli_Meats
25231110	Beef, sliced, prepackaged or deli, luncheon meat	1	1	1	1	1	1	0	Formed_Deli_Meats
25231120	Beef, prepackaged or deli, luncheon meat, reduced sodium	0	0	0	0	0	0	1	Formed_Deli_Meats

25240000	Meat spread or potted meat, NFS	1	1	1	1	1	1	1	Formed_Deli_Meats
25240110	Chicken salad spread	1	1	1	1	1	1	1	Formed_Deli_Meats
25240210	Ham, deviled or potted	1	1	1	1	1	1	0	Formed_Deli_Meats
25240220	Ham salad spread	1	1	1	1	1	1	1	Formed_Deli_Meats
25240310	Roast beef spread	1	1	1	1	1	1	0	Formed_Deli_Meats
25240320	Corned beef spread	1	1	1	1	1	1	0	Formed_Deli_Meats
27560000	Luncheon meat sandwich, NFS, with spread	1	1	1	1	1	1	0	Formed_Deli_Meats
27560000	Luncheon meat sandwich, NFS, with spread	0	0	0	0	0	0	1	Formed_Deli_Meats
27560110	Bologna sandwich, with spread	1	1	1	1	1	1	0	Formed_Deli_Meats
27560110	Bologna sandwich, with spread	0	0	0	0	0	0	1	Formed_Deli_Meats
27560120	Bologna and cheese sandwich, with spread	1	1	1	1	1	1	0	Formed_Deli_Meats
27560120	Bologna and cheese sandwich, with spread	0	0	0	0	0	0	1	Formed_Deli_Meats
27560300	Corn dog (frankfurter or hot dog with cornbread coating)	1	1	1	1	1	1	0	Formed_Deli_Meats
27560300	Corn dog, frankfurter or hot dog with cornbread coating	0	0	0	0	0	0	1	Formed_Deli_Meats
27560310	Corny dog, with chili, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560320	Frankfurter or hot dog, plain, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560330	Frankfurter or hot dog, with cheese, plain, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560350	Pig in a blanket (frankfurter or hot dog wrapped in dough)	1	1	1	1	1	1	0	Formed_Deli_Meats
27560350	Pig in a blanket, frankfurter or hot dog wrapped in dough	0	0	0	0	0	0	1	Formed_Deli_Meats
27560360	Frankfurter or hot dog, with chili, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560370	Frankfurter or hot dog with chili and cheese, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560380	Pochito (frankfurter or hot dog and beef chili wrapped in tortilla)	1	1	1	1	0	0	0	Formed_Deli_Meats
27560400	Chicken frankfurter or hot dog, plain, on bun	1	1	1	1	0	0	0	Formed_Deli_Meats
27560910	Cold cut submarine sandwich, with cheese, lettuce and tomato	0	1	0	0	0	0	0	Formed_Deli_Meats
27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato and spread	0	0	1	1	1	1	0	Formed_Deli_Meats
27560910	Submarine, cold cut sandwich, with lettuce and tomato	1	0	0	0	0	0	0	Formed_Deli_Meats
27563010	Meat spread or potted meat sandwich	1	1	1	1	1	1	1	Formed_Deli_Meats
27564000	Frankfurter or hot dog sandwich, NFS, plain, on white bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564000	Frankfurter or hot dog sandwich, NFS, plain, on wheat bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564001	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564002	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats

27564002	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564003	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564003	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564004	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564004	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564010	Frankfurter or hot dog sandwich, NFS, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564010	Frankfurter or hot dog sandwich, NFS, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564020	Frankfurter or hot dog sandwich, NFS, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564020	Frankfurter or hot dog sandwich, NFS, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564030	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564030	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564030	Frankfurter or hot dog sandwich, NFS, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564040	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564040	Frankfurter or hot dog sandwich, NFS, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564050	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564050	Frankfurter or hot dog sandwich, NFS, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564060	Frankfurter or hot dog sandwich, beef, plain, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564060	Frankfurter or hot dog sandwich, beef, plain, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564060	Frankfurter or hot dog sandwich, beef, plain, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564061	Frankfurter or hot dog sandwich, beef, plain, on wheat bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564062	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564062	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564063	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564063	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats

27564064	Frankfurter or hot dog sandwich, beef, plain, on multigrain bun	0	0	0	0	0	1	1 Formed_Deli_Meats
27564070	Frankfurter or hot dog sandwich, beef, plain, on white bread	0	0	0	0	0	0	1 Formed_Deli_Meats
27564070	Frankfurter or hot dog sandwich, beef, plain, on white bread	0	0	0	0	1	1	0 Formed_Deli_Meats
27564080	Frankfurter or hot dog sandwich, beef, plain, on wheat bread	0	0	0	0	0	0	1 Formed_Deli_Meats
27564080	Frankfurter or hot dog sandwich, beef, plain, on wheat bread	0	0	0	0	1	1	0 Formed_Deli_Meats
27564090	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread	0	0	0	0	0	1	0 Formed_Deli_Meats
27564090	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread	0	0	0	0	0	0	1 Formed_Deli_Meats
27564090	Frankfurter or hot dog sandwich, beef, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0 Formed_Deli_Meats
27564100	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bread	0	0	0	0	0	0	1 Formed_Deli_Meats
27564100	Frankfurter or hot dog sandwich, beef, plain, on whole grain white bread	0	0	0	0	1	1	0 Formed_Deli_Meats
27564110	Frankfurter or hot dog sandwich, beef, plain, on multigrain bread	0	0	0	0	0	0	1 Formed_Deli_Meats
27564110	Frankfurter or hot dog sandwich, beef, plain, on multigrain bread	0	0	0	0	1	1	0 Formed_Deli_Meats
27564120	Frankfurter or hot dog sandwich, beef and pork, plain, on white bun	0	0	0	0	0	0	1 Formed_Deli_Meats
27564120	Frankfurter or hot dog sandwich, beef and pork, plain, on white bun	0	0	0	0	0	1	0 Formed_Deli_Meats
27564120	Frankfurter or hot dog sandwich, beef and pork, plain, on bun	0	0	0	0	1	0	0 Formed_Deli_Meats
27564121	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bun	0	0	0	0	0	0	1 Formed_Deli_Meats
27564121	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bun	0	0	0	0	0	1	0 Formed_Deli_Meats
27564122	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bun	0	0	0	0	0	0	1 Formed_Deli_Meats
27564122	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bun	0	0	0	0	0	1	0 Formed_Deli_Meats
27564123	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bun	0	0	0	0	0	1	0 Formed_Deli_Meats
27564123	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bun	0	0	0	0	0	0	1 Formed_Deli_Meats
27564124	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bun	0	0	0	0	0	0	1 Formed_Deli_Meats
27564124	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bun	0	0	0	0	0	1	0 Formed_Deli_Meats

27564130	Frankfurter or hot dog sandwich, beef and pork, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564130	Frankfurter or hot dog sandwich, beef and pork, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564140	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564140	Frankfurter or hot dog sandwich, beef and pork, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564150	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564150	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564150	Frankfurter or hot dog sandwich, beef and pork, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564160	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564160	Frankfurter or hot dog sandwich, beef and pork, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564170	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564170	Frankfurter or hot dog sandwich, beef and pork, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564180	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564180	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564180	Frankfurter or hot dog sandwich, meat and poultry, plain, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564181	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564181	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564182	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564182	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564183	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564183	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564184	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564184	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats

27564190	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564190	Frankfurter or hot dog sandwich, meat and poultry, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564200	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564200	Frankfurter or hot dog sandwich, meat and poultry, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564210	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564210	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564210	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564220	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564220	Frankfurter or hot dog sandwich, meat and poultry, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564230	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564230	Frankfurter or hot dog sandwich, meat and poultry, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564240	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564240	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564240	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564241	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564241	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564242	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564242	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564243	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564243	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564244	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats

27564244	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564250	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564250	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564260	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564260	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564270	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564270	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564270	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564280	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564280	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564290	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564290	Frankfurter or hot dog sandwich, chicken and/or turkey, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564300	Frankfurter or hot dog sandwich, reduced fat or light, plain, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564301	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564301	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564302	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564302	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats

27564303	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564303	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564304	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564304	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564310	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564310	Frankfurter or hot dog sandwich, reduced fat or light, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564320	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564320	Frankfurter or hot dog sandwich, reduced fat or light, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564330	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564330	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564330	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564340	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564340	Frankfurter or hot dog sandwich, reduced fat or light, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564350	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564350	Frankfurter or hot dog sandwich, reduced fat or light, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564360	Frankfurter or hot dog sandwich, fat free, plain, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564360	Frankfurter or hot dog sandwich, fat free, plain, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564360	Frankfurter or hot dog sandwich, fat free, plain, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564361	Frankfurter or hot dog sandwich, fat free, plain, on wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564361	Frankfurter or hot dog sandwich, fat free, plain, on wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats

27564362	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564362	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564363	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564363	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564364	Frankfurter or hot dog sandwich, fat free, plain, on multigrain bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564370	Frankfurter or hot dog sandwich, fat free, plain, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564370	Frankfurter or hot dog sandwich, fat free, plain, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564380	Frankfurter or hot dog sandwich, fat free, plain, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564380	Frankfurter or hot dog sandwich, fat free, plain, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564390	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564390	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564390	Frankfurter or hot dog sandwich, fat free, plain, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564400	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564400	Frankfurter or hot dog sandwich, fat free, plain, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564410	Frankfurter or hot dog sandwich, fat free, plain, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564410	Frankfurter or hot dog sandwich, fat free, plain, on multigrain bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564440	Frankfurter or hot dog sandwich, with chili, on white bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564440	Frankfurter or hot dog sandwich, with chili, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564441	Frankfurter or hot dog sandwich, with chili, on wheat bun	0	0	0	0	0	1	1	Formed_Deli_Meats
27564442	Frankfurter or hot dog sandwich, with chili, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564442	Frankfurter or hot dog sandwich, with chili, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564443	Frankfurter or hot dog sandwich, with chili, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564443	Frankfurter or hot dog sandwich, with chili, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564444	Frankfurter or hot dog sandwich, with chili, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats

27564444	Frankfurter or hot dog sandwich, with chili, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564450	Frankfurter or hot dog sandwich, with chili, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564450	Frankfurter or hot dog sandwich, with chili, on white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564460	Frankfurter or hot dog sandwich, with chili, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564460	Frankfurter or hot dog sandwich, with chili, on wheat bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564470	Frankfurter or hot dog sandwich, with chili, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564470	Frankfurter or hot dog sandwich, with chili, on whole wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564470	Frankfurter or hot dog sandwich, with chili, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564480	Frankfurter or hot dog sandwich, with chili, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564480	Frankfurter or hot dog sandwich, with chili, on whole grain white bread	0	0	0	0	1	1	0	Formed_Deli_Meats
27564490	Frankfurter or hot dog sandwich, with chili, on multigrain bread	0	0	0	0	0	1	1	Formed_Deli_Meats
27564490	Frankfurter or hot dog sandwich, with chili, on multi-grain bread	0	0	0	0	1	0	0	Formed_Deli_Meats
27564500	Frankfurter or hot dog sandwich, with meatless chili, on white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564500	Frankfurter or hot dog sandwich, with meatless chili, on white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564500	Frankfurter or hot dog sandwich, with vegetarian chili, on bun	0	0	0	0	1	0	0	Formed_Deli_Meats
27564501	Frankfurter or hot dog sandwich, with meatless chili, on wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564501	Frankfurter or hot dog sandwich, with meatless chili, on wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564502	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564502	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564503	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564503	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bun	0	0	0	0	0	1	0	Formed_Deli_Meats
27564504	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bun	0	0	0	0	0	0	1	Formed_Deli_Meats
27564504	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bun	0	0	0	0	0	1	0	Formed_Deli_Meats

27564510	Frankfurter or hot dog sandwich, with meatless chili, on white bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564510	Frankfurter or hot dog sandwich, with meatless chili, on white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564510	Frankfurter or hot dog sandwich, with vegetarian chili, on white bread	0	0	0	0	1	0	0	Formed_Deli_Meats
27564520	Frankfurter or hot dog sandwich, with meatless chili, on wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564520	Frankfurter or hot dog sandwich, with meatless chili, on wheat bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564520	Frankfurter or hot dog sandwich, with vegetarian chili, on wheat bread	0	0	0	0	1	0	0	Formed_Deli_Meats
27564530	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564530	Frankfurter or hot dog sandwich, with meatless chili, on whole wheat bread, NS as to 100%	0	0	0	0	1	0	0	Formed_Deli_Meats
27564540	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564540	Frankfurter or hot dog sandwich, with meatless chili, on whole grain white bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564540	Frankfurter or hot dog sandwich, with vegetarian chili, on whole grain white bread	0	0	0	0	1	0	0	Formed_Deli_Meats
27564550	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bread	0	0	0	0	0	1	0	Formed_Deli_Meats
27564550	Frankfurter or hot dog sandwich, with meatless chili, on multigrain bread	0	0	0	0	0	0	1	Formed_Deli_Meats
27564550	Frankfurter or hot dog sandwich, with vegetarian chili, on multigrain bread	0	0	0	0	1	0	0	Formed_Deli_Meats
74406010	Barbecue sauce	1	1	1	1	1	1	1	BBQ_Sauce
74406050	Barbecue sauce, low sodium	1	1	1	1	0	0	0	BBQ_Sauce
74406050	Barbecue sauce, reduced sodium	0	0	0	0	1	0	0	BBQ_Sauce
93106000	Alcoholic malt beverage, sweetened	0	0	0	0	1	1	1	Malt_Beverages
93106010	Alcoholic malt beverage, higher alcohol, sweetened	0	0	0	0	0	1	1	Malt_Beverages
93106100	Alcoholic malt beverage	0	0	0	0	0	1	1	Malt_Beverages
93106500	Hard cider	0	0	0	0	0	1	1	Malt_Beverages
93301000	Cocktail, NFS	0	0	0	0	1	1	1	Premixed_Cocktails
93301000	Cocktail, NFS	1	1	1	1	0	0	0	Premixed_Cocktails
93301100	Margarita	1	1	1	1	1	1	1	Premixed_Cocktails
93301180	Mixed Drinks (for recipe modifications)	1	1	1	1	1	0	0	Premixed_Cocktails
93301270	Fruit punch, alcoholic	1	1	1	1	1	1	1	Premixed_Cocktails
93301500	Frozen daiquiri	1	1	1	1	1	1	1	Premixed_Cocktails
93301510	Frozen margarita	1	1	1	1	1	1	1	Premixed_Cocktails
74401010	Tomato catsup	1	1	1	1	1	1	1	Ketchup
74401110	Tomato catsup, low sodium	1	1	1	1	0	0	0	Ketchup
74401110	Tomato catsup, reduced sodium	0	0	0	0	1	1	1	Ketchup
41435300	Balance Original Bar	0	0	1	1	0	0	0	Cereal_Bars

41435500	Clif Bar	0	0	1	1	0	0	0	Cereal_Bars
53540000	Breakfast bar, NFS	1	1	1	1	0	0	0	Cereal_Bars
53540200	Breakfast bar, cereal crust with fruit filling, lowfat	1	1	1	1	0	0	0	Cereal_Bars
53540250	Breakfast bar, cereal crust with fruit filling, fat free	1	0	0	0	0	0	0	Cereal_Bars
53540500	Breakfast bar, date, with yogurt coating	1	1	1	1	0	0	0	Cereal_Bars
53540700	Kellogg's Special K bar	0	1	1	1	0	0	0	Cereal_Bars
53540800	Kashi GOLEAN Chewy Bars	0	0	1	1	0	0	0	Cereal_Bars
53540804	Kashi GOLEAN Crunchy Bars	0	0	1	1	0	0	0	Cereal_Bars
53541002	Quaker Chewy 90 Calorie Granola Bar	0	0	0	1	0	0	0	Cereal_Bars
53541004	Quaker Chewy 25% Less Sugar Granola Bar	0	0	0	1	0	0	0	Cereal_Bars
53541200	Meal replacement bar	0	0	1	1	0	0	0	Cereal_Bars
53541200	Meal replacement bar	1	1	0	0	0	0	0	Cereal_Bars
53541300	Slim Fast Original Meal Bar	0	0	0	1	0	0	0	Cereal_Bars
53542000	Snack bar, oatmeal	0	0	1	1	0	0	0	Cereal_Bars
53542100	Granola bar, oats, sugar, raisins, coconut	1	1	1	0	0	0	0	Cereal_Bars
53542100	Granola bar, NFS	0	0	0	1	0	0	0	Cereal_Bars
53542200	Granola bar, lowfat, NFS	0	0	0	1	0	0	0	Cereal_Bars
53542200	Granola bar, oats, fruit and nuts, lowfat	1	1	1	0	0	0	0	Cereal_Bars
53542210	Granola bar, nonfat	1	1	1	1	0	0	0	Cereal_Bars
53543000	Granola bar, oats, reduced sugar	0	0	1	0	0	0	0	Cereal_Bars
53543000	Granola bar, reduced sugar, NFS	0	0	0	1	0	0	0	Cereal_Bars
53543100	Granola bar, peanuts, oats, sugar, wheat germ	1	1	1	1	0	0	0	Cereal_Bars
53544200	Granola bar, chocolate- coated	1	1	0	0	0	0	0	Cereal_Bars
53544200	Granola bar, chocolate- coated, NFS	0	0	1	1	0	0	0	Cereal_Bars
53544210	Granola bar, with coconut, chocolate-coated	1	1	1	1	0	0	0	Cereal_Bars
53544220	Granola bar with nuts, chocolate-coated	1	1	1	1	0	0	0	Cereal_Bars
53544230	Granola bar, oats, nuts, coated with non-chocolate coating	0	0	1	1	0	0	0	Cereal_Bars
53544250	Granola bar, coated with non- chocolate coating	1	1	1	1	0	0	0	Cereal_Bars
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating	1	1	1	1	0	0	0	Cereal_Bars
53544400	Granola bar, with rice cereal Cereal or granola bar	1	1	1	1	0	0	0	Cereal_Bars
53710700	(Kellogg's Special K bar)	0	0	0	0	0	0	1	Cereal_Bars
53710700	Kellogg's Special K bar	0	0	0	0	1	1	0	Cereal_Bars
53710800	Kashi GOLEAN Chewy Bars	0	0	0	0	1	1	0	Cereal_Bars
53710804	Kashi GOLEAN Crunchy Bars	0	0	0	0	1	1	0	Cereal_Bars
53711002	Cereal or granola bar (Quaker Chewy 90 Calorie Granola Bar)	0	0	0	0	0	0	1	Cereal_Bars
53711002	Quaker Chewy 90 Calorie Granola Bar	0	0	0	0	1	1	0	Cereal_Bars
53711004	Cereal or granola bar (Quaker Chewy 25% Less Sugar Granola Bar)	0	0	0	0	0	0	1	Cereal_Bars
53711004	Quaker Chewy 25% Less Sugar Granola Bar	0	0	0	0	1	1	0	Cereal_Bars
53712000	Snack bar, oatmeal	0	0	0	0	1	1	1	Cereal_Bars
53712100	Cereal or Granola bar, NFS	0	0	0	0	0	0	1	Cereal_Bars
53712100	Granola bar, NFS	0	0	0	0	1	1	0	Cereal_Bars
53712200	Cereal or granola bar, lowfat, NFS	0	0	0	0	0	0	1	Cereal_Bars
53712200	Granola bar, lowfat, NFS	0	0	0	0	1	1	0	Cereal_Bars
53712210	Cereal or granola bar, nonfat	0	0	0	0	0	0	1	Cereal_Bars

53712210	Granola bar, nonfat Cereal or granola bar,	0	0	0	0	1	1	0 Cereal_Bars
53713000	reduced sugar, NFS Granola bar, reduced sugar,	0	0	0	0	0	0	1 Cereal_Bars
53713000	NFS Cereal or granola bar,	0	0	0	0	1	1	0 Cereal_Bars
53713100	peanuts , oats, sugar, wheat germ	0	0	0	0	0	0	1 Cereal_Bars
53713100	Granola bar, peanuts , oats, sugar, wheat germ	0	0	0	0	1	1	0 Cereal_Bars
53714200	Cereal or granola bar, chocolate coated, NFS	0	0	0	0	0	0	1 Cereal_Bars
53714200	Granola bar, chocolate- coated, NFS	0	0	0	0	1	1	0 Cereal_Bars
53714210	Cereal or granola bar, with coconut, chocolate coated	0	0	0	0	0	0	1 Cereal_Bars
53714210	Granola bar, with coconut, chocolate-coated	0	0	0	0	1	1	0 Cereal_Bars
53714220	Cereal or granola bar with nuts, chocolate coated	0	0	0	0	0	0	1 Cereal_Bars
53714220	Granola bar with nuts, chocolate-coated	0	0	0	0	1	1	0 Cereal_Bars
53714230	Cereal or granola bar, oats, nuts, coated with non- chocolate coating	0	0	0	0	0	0	1 Cereal_Bars
53714230	Granola bar, oats, nuts, coated with non-chocolate coating	0	0	0	0	1	1	0 Cereal_Bars
53714250	Cereal or granola bar, coated with non-chocolate coating	0	0	0	0	0	0	1 Cereal_Bars
53714250	Granola bar, coated with non- chocolate coating	0	0	0	0	1	1	0 Cereal_Bars
53714300	Cereal or granola bar, high fiber, coated with non- chocolate yogurt coating	0	0	0	0	0	0	1 Cereal_Bars
53714300	Granola bar, high fiber, coated with non-chocolate yogurt coating	0	0	0	0	1	1	0 Cereal_Bars
53714400	Cereal or granola bar, with rice cereal	0	0	0	0	0	0	1 Cereal_Bars
53714400	Granola bar, with rice cereal	0	0	0	0	1	1	0 Cereal_Bars
53714500	Breakfast bar, NFS Breakfast bar, date, with yogurt coating	0	0	0	0	1	1	1 Cereal_Bars
53714510	Breakfast bar, cereal crust with fruit filling, lowfat	0	0	0	0	1	1	1 Cereal_Bars
53720100	Balance Original Bar Nutrition bar (Balance Original Bar)	0	0	0	0	0	0	1 Cereal_Bars
53720200	Clif Bar	0	0	0	0	1	1	0 Cereal_Bars
53720200	Nutrition bar (Clif Bar)	0	0	0	0	0	0	1 Cereal_Bars
53720300	Nutrition bar (PowerBar)	0	0	0	0	0	0	1 Cereal_Bars
53720300	PowerBar	0	0	0	0	1	1	0 Cereal_Bars
53720400	Nutrition bar (Slim Fast Original Meal Bar)	0	0	0	0	0	0	1 Cereal_Bars
53720400	Slim Fast Original Meal Bar	0	0	0	0	1	1	0 Cereal_Bars
53720800	Nutrition bar (Zone Perfect Classic Crunch)	0	0	0	0	0	0	1 Cereal_Bars
53720800	Zone Perfect Classic Crunch nutrition bar	0	0	0	0	1	1	0 Cereal_Bars
53729000	Nutrition bar or meal replacement bar, NFS	0	0	0	0	1	1	1 Cereal_Bars
93404000	Wine cooler	1	1	1	1	1	1	1 Wine_Coolers
93405000	Wine spritzer	1	1	1	1	1	1	1 Wine_Coolers
62109100	Cranberries, dried	1	1	1	1	1	1	1 Dried_Cranberries
57100100	Cereal, ready-to-eat, NFS Character cereals, TV or movie, General Mills	1	1	1	1	1	1	1 Presweetened_Cereal
57100400	Character cereals, TV or movie, Kellogg's	0	1	1	1	0	0	0 Presweetened_Cereal

Character cereals, TV or							
57100500 movie, Kelloggs	1	0	0	0	0	0	0 Presweetened_Cereal
57101000 All-Bran	1	1	1	1	1	1	0 Presweetened_Cereal
57101000 Cereal (Kellogg's All-Bran)	0	0	0	0	0	0	1 Presweetened_Cereal
57101020 All-Bran with Extra Fiber	1	1	1	1	0	0	0 Presweetened_Cereal
57102000 Alpen	1	1	1	1	1	1	0 Presweetened_Cereal
57102000 Cereal (Alpen)	0	0	0	0	0	0	1 Presweetened_Cereal
57103000 Alpha-Bits	1	1	1	1	1	1	0 Presweetened_Cereal
57103000 Cereal (Post Alpha-Bits)	0	0	0	0	0	0	1 Presweetened_Cereal
Alpha-bits with							
57103020 marshmallows	1	1	1	1	1	1	0 Presweetened_Cereal
57103100 Apple Cinnamon Cheerios	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills							
57103100 Cheerios Apple Cinnamon)	0	0	0	0	0	0	1 Presweetened_Cereal
Apple Cinnamon Squares							
Mini-Wheats, Kellogg's							
(formerly Apple Cinnamon							
Squares)							
57103500	1	1	1	1	0	0	0 Presweetened_Cereal
57104000 Apple Jacks	1	1	1	1	1	1	0 Presweetened_Cereal
57104000 Cereal (Kellogg's Apple Jacks)	0	0	0	0	0	0	1 Presweetened_Cereal
Banana Nut Crunch Cereal							
(Post)							
57106050	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Post Great Grains							
Banana Nut Crunch)							
57106050	0	0	0	0	0	0	1 Presweetened_Cereal
57106060 Banana Nut Cheerios	0	0	0	0	1	1	0 Presweetened_Cereal
Cereal (General Mills							
57106060 Cheerios Banana Nut)	0	0	0	0	0	0	1 Presweetened_Cereal
57106100 Basic 4	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills Basic							
4)							
57106100	0	0	0	0	0	0	1 Presweetened_Cereal
57106250 Berry Berry Kix	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills Kix							
Berry Berry)							
57106250	0	0	0	0	0	0	1 Presweetened_Cereal
57106260 Berry Burst Cheerios	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills							
57106260 Cheerios Berry Burst)	0	0	0	0	0	0	1 Presweetened_Cereal
57106530 Blueberry Morning, Post	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Post Selects							
57106530 Blueberry Morning)	0	0	0	0	0	0	1 Presweetened_Cereal
57107000 Booberry	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills Boo							
Berry)							
57107000	0	0	0	0	0	0	1 Presweetened_Cereal
All-Bran Bran Buds, Kellogg's							
(formerly Bran Buds)							
57110000	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Kellogg's All-Bran							
Bran Buds)							
57110000	0	0	0	0	0	0	1 Presweetened_Cereal
57111000 Bran Chex	1	1	1	1	1	0	0 Presweetened_Cereal
57117000 Cap'n Crunch	1	1	1	1	1	1	0 Presweetened_Cereal
57117000 Cereal (Quaker Cap'n Crunch)	0	0	0	0	0	0	1 Presweetened_Cereal
Cap'n Crunch's Christmas							
Crunch							
57117500	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Quaker Christmas							
Crunch)							
57117500	0	0	0	0	0	0	1 Presweetened_Cereal
57119000 Cap'n Crunch's Crunch Berries	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Quaker Cap'n							
Crunch's Crunchberries)							
57119000	0	0	0	0	0	0	1 Presweetened_Cereal
Cap'n Crunch's Peanut Butter							
Crunch							
57120000	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (Quaker Cap'n							
Crunch's Peanut Butter							
Crunch)							
57120000	0	0	0	0	0	0	1 Presweetened_Cereal
Cereal (General Mills							
57123000 Cheerios)	0	0	0	0	0	0	1 Presweetened_Cereal
57123000 Cheerios	1	1	1	1	1	1	0 Presweetened_Cereal
57124000 Chex cereal, NFS	1	1	1	1	1	1	0 Presweetened_Cereal
Cereal (General Mills Chex							
Chocolate)							
57124030	0	0	0	0	0	0	1 Presweetened_Cereal

57124030	Chex Chocolate Cereal (General Mills Chex	0	0	0	0	0	1	0 Presweetened_Cereal
57124050	Cinnamon)	0	0	0	0	0	0	1 Presweetened_Cereal
57124050	Chex Cinnamon Cereal (General Mills	0	0	0	0	1	1	0 Presweetened_Cereal
57124100	Cheerios Chocolate)	0	0	0	0	0	0	1 Presweetened_Cereal
57124100	Chocolate Cheerios Cereal, chocolate flavored,	0	0	0	0	1	1	0 Presweetened_Cereal
57124200	frosted, puffed corn Chocolate flavored frosted	0	0	0	0	0	0	1 Presweetened_Cereal
57124200	puffed corn cereal Cereal (General Mills Lucky	1	1	1	1	1	1	0 Presweetened_Cereal
57124300	Charms Chocolate)	0	0	0	0	0	0	1 Presweetened_Cereal
57124300	Chocolate Lucky Charms Cinnamon Grahams, General	0	0	1	1	1	1	0 Presweetened_Cereal
57124500	Mills Cinnamon Grahams, General	1	0	0	0	0	0	0 Presweetened_Cereal
57124500	Mills	0	1	1	0	0	0	0 Presweetened_Cereal
57124900	Cereal (Kellogg's Cinnabon)	0	0	0	0	0	0	1 Presweetened_Cereal
57124900	Cinnabon cereal Cereal (General Mills	0	0	0	0	0	1	0 Presweetened_Cereal
57125000	Cinnamon Toast Crunch)	0	0	0	0	0	0	1 Presweetened_Cereal
57125000	Cinnamon Toast Crunch Cereal (General Mills 25%	1	1	1	1	1	1	0 Presweetened_Cereal
57125010	Crunch) Cinnamon Toast Crunch	0	0	0	0	0	0	1 Presweetened_Cereal
57125010	Reduced Sugar Cereal (General Mills Honey	0	0	1	1	1	1	0 Presweetened_Cereal
57125900	Nut Clusters)	0	0	0	0	0	0	1 Presweetened_Cereal
57125900	Honey Nut Clusters (formerly called Clusters)	1	1	1	1	1	1	0 Presweetened_Cereal
57126000	Cereal (Kellogg's Cocoa Krispies)	0	0	0	0	0	0	1 Presweetened_Cereal
57126000	Cocoa Krispies	1	1	1	1	1	1	0 Presweetened_Cereal
57126500	Cocoa Blasts, Quaker	1	1	1	1	0	0	0 Presweetened_Cereal
57127000	Cereal (Post Cocoa Pebbles)	0	0	0	0	0	0	1 Presweetened_Cereal
57127000	Cocoa Pebbles Cereal (General Mills Cocoa	1	1	1	1	1	1	0 Presweetened_Cereal
57128000	Puffs)	0	0	0	0	0	0	1 Presweetened_Cereal
57128000	Cocoa Puffs Cereal (General Mills 25%	1	1	1	1	1	1	0 Presweetened_Cereal
57128005	Less Sugar Cocoa Puffs)	0	0	0	0	0	0	1 Presweetened_Cereal
57128005	Cocoa Puffs, reduced sugar Complete Oat Bran Flakes,	0	0	0	0	1	1	0 Presweetened_Cereal
57128880	Kellogg's (formerly Common Sense Oat Bran, plain) Cereal (General Mills Cookie	1	1	1	1	0	0	0 Presweetened_Cereal
57130000	Crisp)	0	0	0	0	0	0	1 Presweetened_Cereal
57130000	Cookie-Crisp Cereal (Quaker Corn Bran	1	1	1	1	1	1	0 Presweetened_Cereal
57131000	Crunch)	0	0	0	0	0	0	1 Presweetened_Cereal
57131000	Crunchy Corn Bran, Quaker Cereal (General Mills Chex	1	1	1	1	1	1	0 Presweetened_Cereal
57132000	Corn)	0	0	0	0	0	0	1 Presweetened_Cereal
57132000	Corn Chex	1	1	1	1	1	1	0 Presweetened_Cereal
57134000	Cereal, corn flakes	0	0	0	0	0	0	1 Presweetened_Cereal
57134000	Corn flakes, NFS	1	1	1	1	1	1	0 Presweetened_Cereal
57134090	Corn flakes, low sodium	1	1	1	1	1	0	0 Presweetened_Cereal
57135000	Cereal (Kellogg's Corn Flakes)	0	0	0	0	0	0	1 Presweetened_Cereal
57135000	Corn flakes, Kellogg	1	0	0	0	0	0	0 Presweetened_Cereal
57135000	Corn flakes, Kellogg's	0	1	1	1	1	1	0 Presweetened_Cereal
57137000	Cereal, corn puffs	0	0	0	0	0	0	1 Presweetened_Cereal
57137000	Corn Puffs	1	1	1	1	1	1	0 Presweetened_Cereal
57138000	Total Corn Flakes Cereal (General Mills Count	1	1	1	1	0	0	0 Presweetened_Cereal
57139000	Chocula)	0	0	0	0	0	0	1 Presweetened_Cereal
57139000	Count Chocula Cereal (Kellogg's Cracklin'	1	1	1	1	1	1	0 Presweetened_Cereal
57143000	Oat Bran)	0	0	0	0	0	0	1 Presweetened_Cereal

57143000	Cracklin' Oat Bran Cereal (Post Great Grains,	1	1	1	1	1	1	0	Presweetened_Cereal
57143500	Cranberry Almond Crunch) Cranberry Almond Crunch,	0	0	0	0	0	0	1	Presweetened_Cereal
57143500	Post	0	1	1	1	1	1	0	Presweetened_Cereal
57144000	Crisp Crunch	1	1	1	1	1	1	0	Presweetened_Cereal
57148000	Cereal (Kellogg's Crispix)	0	0	0	0	0	0	1	Presweetened_Cereal
57148000	Crispix	1	1	1	1	1	1	0	Presweetened_Cereal
57148500	Cereal, crispy brown rice	0	0	0	0	0	0	1	Presweetened_Cereal
57148500	Crispy Brown Rice Cereal Harmony cereal, General	1	1	1	1	1	1	0	Presweetened_Cereal
57148600	Mills	1	0	0	0	0	0	0	Presweetened_Cereal
57148600	Harmony cereal, General Mills	0	1	1	0	0	0	0	Presweetened_Cereal
57151000	Cereal, crispy rice	0	0	0	0	0	0	1	Presweetened_Cereal
57151000	Crispy Rice	1	1	1	1	1	1	0	Presweetened_Cereal
57152000	Crispy Wheats'n Raisins Curves Fruit and Nut Crunch	1	1	1	1	0	0	0	Presweetened_Cereal
57160000	Cereal	0	0	1	1	0	0	0	Presweetened_Cereal
57201800	Disney cereals, Kellogg's Cereal (General Mills Dora	1	1	1	1	0	0	0	Presweetened_Cereal
57201900	The Explorer)	0	0	0	0	0	0	1	Presweetened_Cereal
57201900	Dora the Explorer Cereal	0	0	1	1	1	1	0	Presweetened_Cereal
57206000	Cereal (Familia)	0	0	0	0	0	0	1	Presweetened_Cereal
57206000	Familia Cereal (General Mills Fiber	1	1	1	1	1	1	0	Presweetened_Cereal
57206700	One)	0	0	0	0	0	0	1	Presweetened_Cereal
57206700	Fiber One Cereal (General Mills Fiber	1	1	1	1	1	1	0	Presweetened_Cereal
57206705	One Caramel Delight)	0	0	0	0	0	0	1	Presweetened_Cereal
57206705	Fiber One Caramel Delight Cereal (General Mills Fiber	0	0	0	0	1	1	0	Presweetened_Cereal
57206710	One Honey Clusters)	0	0	0	0	0	0	1	Presweetened_Cereal
57206710	Fiber One Honey Clusters Cereal (General Mills Fiber	0	0	0	0	1	1	0	Presweetened_Cereal
57206715	One Raisin Bran Clusters)	0	0	0	0	0	0	1	Presweetened_Cereal
57206715	Fiber One Raisin Bran Clusters	0	0	0	0	1	1	0	Presweetened_Cereal
57206800	Cereal (Health Valley Fiber 7 Flakes)	0	0	0	0	0	0	1	Presweetened_Cereal
57206800	Fiber 7 Flakes, Health Valley Bran Flakes, NFS (formerly	1	1	1	1	1	1	0	Presweetened_Cereal
57207000	40% Bran Flakes, NFS)	1	1	1	1	1	1	0	Presweetened_Cereal
57207000	Cereal, bran flakes All-Bran Complete Wheat	0	0	0	0	0	0	1	Presweetened_Cereal
57208000	Flakes, Kellogg's Cereal (Kellogg's All-Bran	0	0	0	1	1	1	0	Presweetened_Cereal
57208000	Complete Wheat Flakes) Complete Wheat Bran	0	0	0	0	0	0	1	Presweetened_Cereal
57208000	Flakes, Kellogg's (formerly 40% Bran Flakes)	1	1	1	0	0	0	0	Presweetened_Cereal
57209000	Cereal (Post Bran Flakes) Natural Bran Flakes, Post	0	0	0	0	0	0	1	Presweetened_Cereal
57209000	(formerly called 40% Bran Flakes, Post)	1	1	1	1	1	1	0	Presweetened_Cereal
57211000	Cereal (General Mills Frankenberry)	0	0	0	0	0	0	1	Presweetened_Cereal
57211000	Frankenberry French Toast Crunch, General	1	1	1	1	1	1	0	Presweetened_Cereal
57212100	Mills Cereal (Kellogg's Froot	1	1	1	1	0	0	0	Presweetened_Cereal
57213000	Loops)	0	0	0	0	0	0	1	Presweetened_Cereal
57213000	Froot Loops	1	1	1	1	1	1	0	Presweetened_Cereal
57213005	Froot Loops Cereal Straws Cereal (Kellogg's Froot Loops	0	0	1	1	0	0	0	Presweetened_Cereal
57213010	Marshmallow)	0	0	0	0	0	0	1	Presweetened_Cereal
57213010	Froot Loops Marshmallow Cereal (General Mills	0	0	0	0	0	1	0	Presweetened_Cereal
57213850	Cheerios Frosted)	0	0	0	0	0	0	1	Presweetened_Cereal
57213850	Frosted Cheerios	1	1	1	1	1	1	0	Presweetened_Cereal
57213900	Frosted Chex	0	1	1	1	0	0	0	Presweetened_Cereal

Cereal (Kellogg's Frosted								
57214000 Mini-Wheats)	0	0	0	0	0	0	1	Presweetened_Cereal
57214000 Frosted Mini-Wheats	1	1	1	1	1	1	0	Presweetened_Cereal
57214100 Frosted Wheat Bites	1	1	1	1	1	1	0	Presweetened_Cereal
57215000 Frosty O's	1	1	1	1	1	1	0	Presweetened_Cereal
57216000 Cereal, frosted rice	0	0	0	0	0	0	1	Presweetened_Cereal
57216000 Frosted rice, NFS	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Kellogg's Frosted								
57218000 Krispies)	0	0	0	0	0	0	1	Presweetened_Cereal
57218000 Frosted Rice Krispies	1	1	0	0	0	0	0	Presweetened_Cereal
Frosted Rice Krispies,								
57218000 Kellogg's	0	0	1	1	1	1	0	Presweetened_Cereal
57219000 Cereal, fruit and fiber	0	0	0	0	0	0	1	Presweetened_Cereal
57219000 Fruit & Fibre (fiber), NFS	1	1	1	1	1	1	1	Presweetened_Cereal
57221000 Cereal, fiber and fruit	0	0	0	0	0	0	1	Presweetened_Cereal
Fruit & Fibre (fiber) with								
57221000 dates, raisins, and walnuts	1	1	1	1	1	1	0	Presweetened_Cereal
Fruit Harvest cereal,								
57221650 Kellogg's	1	1	1	1	1	0	0	Presweetened_Cereal
57221700 Cereal, fruit rings	0	0	0	0	0	0	1	Presweetened_Cereal
57221700 Fruit Rings, NFS	1	1	1	1	1	1	0	Presweetened_Cereal
57221800 Cereal, fruit whirls	0	0	0	0	0	0	1	Presweetened_Cereal
57221800 Fruit Whirls	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (General Mills								
57221810 Cheerios Fruity)	0	0	0	0	0	0	1	Presweetened_Cereal
57221810 Fruity Cheerios	0	0	1	1	1	1	0	Presweetened_Cereal
57223000 Cereal (Post Fruity Pebbles)	0	0	0	0	0	0	1	Presweetened_Cereal
57223000 Fruity Pebbles	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (General Mills Golden								
57224000 Grahams)	0	0	0	0	0	0	1	Presweetened_Cereal
57224000 Golden Grahams	1	1	1	1	1	1	0	Presweetened_Cereal
57227000 Cereal, granola	0	0	0	0	0	0	1	Presweetened_Cereal
57227000 Granola, NFS	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Kellogg's Low Fat								
57229000 Granola)	0	0	0	0	0	0	1	Presweetened_Cereal
57229000 Granola, lowfat, Kellogg's	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Kellogg's Low Fat								
57229500 Granola with Raisins)	0	0	0	0	0	0	1	Presweetened_Cereal
Granola with Raisins, lowfat,								
57229500 Kellogg's	1	1	1	1	1	1	0	Presweetened_Cereal
57230000 Cereal (Post Grape-Nuts)	0	0	0	0	0	0	1	Presweetened_Cereal
57230000 Grape-Nuts	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Post Grape-Nuts								
57231000 Flakes)	0	0	0	0	0	0	1	Presweetened_Cereal
57231000 Grape-Nut Flakes	1	1	1	0	0	0	0	Presweetened_Cereal
57231000 Grape-Nuts Flakes	0	0	0	1	1	1	0	Presweetened_Cereal
57231100 Grape-Nuts Trail Mix Crunch	0	0	0	0	1	1	0	Presweetened_Cereal
Cereal (Post Great Grains								
57231200 Raisins, Dates, and Pecans)	0	0	0	0	0	0	1	Presweetened_Cereal
Great Grains, Raisin, Date,								
and Pecan Whole Grain								
57231200 Cereal, Post	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Post Great Grains								
57231250 Double Pecan Whole Grain	0	0	0	0	0	0	1	Presweetened_Cereal
Cereal)								
57231250 Great Grains Double Pecan	0	0	0	0	0	0	1	Presweetened_Cereal
Whole Grain Cereal, Post	1	1	1	1	1	1	0	Presweetened_Cereal
Healthy Choice Almond								
57232100 Crunch with raisins, Kellogg's	1	0	0	0	0	0	0	Presweetened_Cereal
Cereal (Post Honey Bunches								
57237100 of Oats Honey Roasted)	0	0	0	0	0	0	1	Presweetened_Cereal
57237100 Honey Bunches of Oats	1	1	1	1	0	0	0	Presweetened_Cereal
Honey Bunches of Oats								
57237100 Honey Roasted Cereal	0	0	0	0	1	1	0	Presweetened_Cereal
Cereal (Post Honey Bunches								
57237200 of Oats with Vanilla	0	0	0	0	0	0	1	Presweetened_Cereal
Bunches)								
57237200 Honey Bunches of Oats with	0	0	0	1	1	1	0	Presweetened_Cereal
Vanilla Clusters, Post	0	0	0	1	1	1	0	Presweetened_Cereal

57237300	Cereal (Post Honey Bunches of Oats with Almonds)	0	0	0	0	0	0	1	Presweetened_Cereal
57237300	Honey Bunches of Oats with Almonds, Post	1	1	1	1	1	1	0	Presweetened_Cereal
57237310	Cereal (Post Honey Bunches of Oats with Pecan Bunches)	0	0	0	0	0	0	1	Presweetened_Cereal
57237310	Honey Bunches of Oats with Pecan Bunches	0	0	0	0	1	1	0	Presweetened_Cereal
57237900	Cereal (Post Honey Bunches of Oats Just Bunches)	0	0	0	0	0	0	1	Presweetened_Cereal
57237900	Honey Bunches of Oats Just Bunches	0	0	0	0	1	1	0	Presweetened_Cereal
57238000	Cereal (Post Honeycomb)	0	0	0	0	0	0	1	Presweetened_Cereal
57238000	Honeycomb, plain	1	1	1	1	1	1	0	Presweetened_Cereal
57239000	Honeycomb, strawberry	1	1	1	1	1	1	0	Presweetened_Cereal
57239100	Cereal (Kellogg's Honey Crunch Corn Flakes)	0	0	0	0	0	0	1	Presweetened_Cereal
57239100	Honey Crunch Corn Flakes, Kellogg's	1	1	1	1	1	1	0	Presweetened_Cereal
57240100	Cereal (General Mills Chex Honey Nut)	0	0	0	0	0	0	1	Presweetened_Cereal
57240100	Honey Nut Chex	1	1	1	1	1	1	0	Presweetened_Cereal
57241000	Cereal (General Mills Cheerios Honey Nut)	0	0	0	0	0	0	1	Presweetened_Cereal
57241000	Honey Nut Cheerios	1	1	1	1	1	1	0	Presweetened_Cereal
57241200	Cereal (Post Shredded Wheat Honey Nut)	0	0	0	0	0	0	1	Presweetened_Cereal
57241200	Honey Nut Shredded Wheat, Post	1	1	1	1	1	1	0	Presweetened_Cereal
57243000	Cereal (Kellogg's Honey Smacks)	0	0	0	0	0	0	1	Presweetened_Cereal
57243000	Honey Smacks, Kellogg's (formerly Smacks; Honey Smacks, Kellogg's (formerly Honey Smacks)	0	1	1	1	1	1	0	Presweetened_Cereal
57243000	Honey Smacks)	1	0	0	0	0	0	0	Presweetened_Cereal
57243870	Jenny O's	1	1	1	1	0	0	0	Presweetened_Cereal
57244000	Just Right	1	1	1	1	0	0	0	Presweetened_Cereal
57245000	Just Right Fruit and Nut (formerly Just Right with raisins, dates, and nuts)	1	1	1	1	0	0	0	Presweetened_Cereal
57250000	Pokemon, Kellogg's	1	0	0	0	0	0	0	Presweetened_Cereal
57301100	Kaboom	1	1	1	1	0	0	0	Presweetened_Cereal
57301500	Cereal (Kashi 7 Whole Grain Puffs)	0	0	0	0	0	0	1	Presweetened_Cereal
57301500	Kashi, Puffed	1	1	1	1	1	1	0	Presweetened_Cereal
57301505	Cereal (Kashi Autumn Wheat)	0	0	0	0	0	0	1	Presweetened_Cereal
57301505	Kashi Autumn Wheat	0	0	1	1	1	1	0	Presweetened_Cereal
57301510	Cereal (Kashi GOLEAN)	0	0	0	0	0	0	1	Presweetened_Cereal
57301510	Kashi GOLEAN	0	0	1	1	1	1	0	Presweetened_Cereal
57301510	Kashi GoLean	0	1	0	0	0	0	0	Presweetened_Cereal
57301511	Cereal (Kashi GOLEAN Crunch)	0	0	0	0	0	0	1	Presweetened_Cereal
57301511	Kashi GOLEAN Crunch	0	0	1	1	1	1	0	Presweetened_Cereal
57301511	Kashi GoLean Crunch	0	1	0	0	0	0	0	Presweetened_Cereal
57301512	Cereal (Kashi GOLEAN Crunch Honey Almond Flax)	0	0	0	0	0	0	1	Presweetened_Cereal
57301512	Kashi GOLEAN Crunch Honey Almond Flax	0	0	1	1	1	1	0	Presweetened_Cereal
57301520	Cereal (Kashi Good Friends)	0	0	0	0	0	0	1	Presweetened_Cereal
57301520	Kashi Good Friends	0	1	1	1	1	1	0	Presweetened_Cereal
57301530	Cereal (Kashi Heart to Heart Honey Toasted Oat)	0	0	0	0	0	0	1	Presweetened_Cereal
57301530	Kashi Heart to Heart	0	1	1	0	0	0	0	Presweetened_Cereal
57301530	Kashi Heart to Heart Honey Toasted Oat	0	0	0	1	1	1	0	Presweetened_Cereal
57301535	Cereal (Kashi Heart to Heart Oat Flakes and Blueberry Clusters)	0	0	0	0	0	0	1	Presweetened_Cereal

57301535	Kashi Heart to Heart Oat Flakes and Blueberry Clusters	0	0	0	0	1	1	0 Presweetened_Cereal
57301540	Cereal (Kashi Honey Sunshine Squares)	0	0	0	0	0	0	1 Presweetened_Cereal
57301540	Kashi Honey Sunshine Cereal (Quaker King Vitaman)	0	0	0	0	1	1	0 Presweetened_Cereal
57302100	King Vitaman Cereal (General Mills Kix)	0	0	0	0	0	0	1 Presweetened_Cereal
57303100	Kix Cereal (General Mills Honey Kix)	1	1	1	1	1	1	0 Presweetened_Cereal
57303105	Honey Kix Cereal (Kellogg's Krave)	0	0	0	0	0	0	1 Presweetened_Cereal
57304100	Cereal (Quaker Life Life (plain and cinnamon))	0	0	0	0	0	0	1 Presweetened_Cereal
57304100	Lucky Charms Cereal (General Mills Lucky Charms)	1	1	1	1	1	1	0 Presweetened_Cereal
57305100	Lucky Charms Cereal, frosted oat cereal with marshmallows	0	0	0	0	0	0	1 Presweetened_Cereal
57305150	Frosted oat cereal with marshmallows Cereal (Malt-O-Meal Blueberry Muffin Tops)	1	1	1	1	1	1	0 Presweetened_Cereal
57305160	Muffin Tops Cereal (Malt-O-Meal Cinnamon Toasters)	0	0	0	0	0	0	1 Presweetened_Cereal
57305165	Toasters Cereal (Malt-O-Meal Coco-Roos)	0	0	0	0	1	1	0 Presweetened_Cereal
57305170	Malt-O-Meal Coco-Roos Cereal (Malt-O-Meal Colossal Crunch)	1	1	1	1	1	1	0 Presweetened_Cereal
57305174	Colossal Crunch Cereal (Malt-O-Meal Cocoa Dyno-Bites)	0	0	0	0	1	1	0 Presweetened_Cereal
57305175	Dyno-Bites Cereal (Malt-O-Meal Corn Bursts)	0	0	0	0	0	0	1 Presweetened_Cereal
57305180	Malt-O-Meal Corn Bursts Cereal (Malt-O-Meal Frosted Rice)	1	1	1	1	1	1	0 Presweetened_Cereal
57305200	Malt-O-Meal Frosted Rice Cereal (Malt-O-Meal Frosted Flakes)	0	0	0	0	0	0	1 Presweetened_Cereal
57305210	Malt-O-Meal Frosted Flakes Cereal (Malt-O-Meal Frosted Mini Spooners)	1	1	1	1	1	1	0 Presweetened_Cereal
57305215	Mini Spooners Cereal (Malt-O-Meal Fruity Dyno-Bites)	0	0	0	0	1	1	0 Presweetened_Cereal
57305300	Dyno-Bites Malt-O-Meal Fruity Dyno-Bites	0	0	1	1	1	1	0 Presweetened_Cereal
57305400	Graham Squares Cereal (Malt-O-Meal Honey Graham Squares)	0	0	0	0	1	1	0 Presweetened_Cereal
57305500	Nut Toasty O's Malt-O-Meal Honey and Nut Toasty O's	0	0	0	0	0	0	1 Presweetened_Cereal
57305500	Stoasty O's Cereal (Malt-O-Meal Marshmallow Mateys)	1	1	1	1	1	1	0 Presweetened_Cereal
57305600	Marshmallow Mateys	0	0	0	0	0	0	1 Presweetened_Cereal

Malt-O-Meal Marshmallow								
57305600 Malt-O-Meal Marshmallow	1	1	1	1	1	1	0	Presweetened_Cereal
57306100 Malt-O-Meal Puffed Rice	1	1	1	1	1	1	0	Presweetened_Cereal
57306120 Malt-O-Meal Puffed Wheat	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Malt-O-Meal Raisin Bran)	0	0	0	0	0	0	1	Presweetened_Cereal
57306130 Malt-O-Meal Raisin Bran	0	0	0	0	1	1	0	Presweetened_Cereal
Cereal (Malt-O-Meal Golden Puffs)	0	0	0	0	0	0	1	Presweetened_Cereal
57306500 Malt-O-Meal Golden Puffs	0	0	0	0	0	0	1	Presweetened_Cereal
(formerly Sugar Puffs)	1	1	1	1	1	1	0	Presweetened_Cereal
57306500 Cereal (Malt-O-Meal Toasted Oat Cereal)	0	0	0	0	0	0	1	Presweetened_Cereal
57306700 Malt-O-Meal Toasted Oat Cereal	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Malt-O-Meal Tootie Fruities)	0	0	0	0	0	0	1	Presweetened_Cereal
57306800 Malt-O-meal Tootie Fruities	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (Post Maple Pecan Crunch)	0	0	0	0	0	0	1	Presweetened_Cereal
57307010 Maple Pecan Crunch Cereal, Post	0	1	1	1	1	1	0	Presweetened_Cereal
57307150 Marshmallow Safari, Quaker	1	1	1	1	0	0	0	Presweetened_Cereal
57307500 Cereal, millet, puffed	0	0	0	0	0	0	1	Presweetened_Cereal
57307500 Millet, puffed	1	1	1	1	1	1	0	Presweetened_Cereal
Mini-Swirlz Cinnamon Bun								
57307600 Cereal, Kellogg's	0	0	1	1	1	0	0	Presweetened_Cereal
57308150 Mueslix cereal, NFS	1	1	1	1	1	1	0	Presweetened_Cereal
57308190 Cereal, muesli	0	0	0	0	0	0	1	Presweetened_Cereal
Muesli with raisins, dates, and almonds	1	0	0	0	0	0	0	Presweetened_Cereal
57308190 Muesli, dried fruit and nuts (formerly Muesli) with raisins, dates, and almonds)	0	1	1	1	1	1	0	Presweetened_Cereal
57308300 Multi Bran Chex	1	1	1	1	1	0	0	Presweetened_Cereal
Cereal (General Mills Cheerios Multigrain)	0	0	0	0	0	0	1	Presweetened_Cereal
57308400 Multi Grain Cheerios	1	1	0	0	0	0	0	Presweetened_Cereal
57308400 MultiGrain Cheerios	0	0	1	1	1	1	0	Presweetened_Cereal
Natural Muesli, Jenny's Cuisine	1	1	1	1	0	0	0	Presweetened_Cereal
57308900 Cereal (Nature Valley Granola)	0	0	0	0	0	0	1	Presweetened_Cereal
Nature Valley Granola, with fruit and nuts	1	1	1	1	1	1	0	Presweetened_Cereal
57309100 Nu System Cuisine Toasted Grain Circles	1	1	1	1	0	0	0	Presweetened_Cereal
57316200 Cereal, nutty nuggets	0	0	0	0	0	0	1	Presweetened_Cereal
Nutty Nuggets, Ralston Purina	1	1	1	1	1	1	0	Presweetened_Cereal
57316200 Cereal (Health Valley Oat Bran Flakes)	0	0	0	0	0	0	1	Presweetened_Cereal
57316300 Oat Bran Flakes, Health Valley	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (General Mills Cheerios Oat Cluster Crunch)	0	0	0	0	0	0	1	Presweetened_Cereal
57316380 Oat Cluster Cheerios Crunch	0	0	0	0	1	1	0	Presweetened_Cereal
Cereal (General Mills Cheerios Protein)	0	0	0	0	0	0	1	Presweetened_Cereal
57316385 Apple Cinnamon Oatmeal Crisp (formerly Oatmeal Crisp with Apples)	1	0	0	0	0	0	0	Presweetened_Cereal
57316410 Oatmeal Crisp, Apple Cinnamon (formerly Oatmeal Crisp with Apples)	0	1	1	1	0	0	0	Presweetened_Cereal
Cereal (General Mills Oatmeal Crisp with Almonds)	0	0	0	0	0	0	1	Presweetened_Cereal
57316450 Oatmeal Crisp with Almonds	1	1	1	1	1	1	0	Presweetened_Cereal
Cereal (General Mills Oatmeal Crisp with Raisins)	0	0	0	0	0	0	1	Presweetened_Cereal

	Oatmeal Crisp, Raisin (formerly Oatmeal Raisin Crisp)	0	1	1	1	1	1	0	Presweetened_Cereal
57316500	Oatmeal Raisin Crisp Cereal (Quaker Honey Graham Oh's)	1	0	0	0	0	0	0	Presweetened_Cereal
57316710	Oh's, Honey Graham	0	0	0	0	0	0	1	Presweetened_Cereal
57316710	Oh's, Fruitangy, Quaker	1	1	1	1	1	1	0	Presweetened_Cereal
57316750	Oh's, Fruitangy, Quaker	1	0	0	0	0	0	0	Presweetened_Cereal
57316750	Oh's, Fruitangy, Quaker	0	1	1	1	0	0	0	Presweetened_Cereal
57318000	100% Bran 100% Natural Cereal, plain, Quaker	1	1	1	1	0	0	0	Presweetened_Cereal
57319000	Sun Country 100% Natural Granola, with Almonds	1	1	1	1	1	0	0	Presweetened_Cereal
57319500	100 % Natural Cereal, with oats, honey and raisins, Quaker	1	1	1	1	1	1	0	Presweetened_Cereal
57320500	Cereal (Quaker Granola with Oats, Honey, and Raisins)	0	0	0	0	0	0	1	Presweetened_Cereal
57320500	100 % Natural Wholegrain Cereal with raisins, lowfat, Quaker	1	1	1	1	1	1	0	Presweetened_Cereal
57321500	Optimum, Nature's Path	1	1	1	1	1	0	0	Presweetened_Cereal
57321700	Optimum Slim, Nature's Path Cereal (Nature's Path Organic Flax Plus)	1	1	1	1	1	0	0	Presweetened_Cereal
57321800	Organic Flax Plus, Nature's Path	0	0	0	0	0	0	1	Presweetened_Cereal
57321900	Organic Flax Plus, Pumpkin Granola, Nature's Path	0	0	0	0	0	1	0	Presweetened_Cereal
57321905	Oreo O's cereal, Post Cereal (Quaker Sweet Crunch)	1	1	1	1	0	0	0	Presweetened_Cereal
57322500	Sweet Crunch, Quaker (formerly called Popeye)	1	1	1	1	1	1	0	Presweetened_Cereal
57323000	Sweet Puffs, Quaker Peanut Butter Toast Crunch, General Mills	1	1	1	0	0	0	0	Presweetened_Cereal
57323000	Cereal (Kellogg's Product 19) Product 19	0	0	0	0	0	0	1	Presweetened_Cereal
57325000	Cereal (Barbara's Puffins) Puffins Cereal	1	1	1	1	1	1	0	Presweetened_Cereal
57326000	Cereal (Quaker Toasted Oat Bran)	0	0	0	0	1	1	0	Presweetened_Cereal
57327450	Quaker Oat Bran Cereal Cereal (Quaker Oatmeal Squares)	1	1	1	1	1	1	0	Presweetened_Cereal
57327450	Quaker Oatmeal Squares (formerly Quaker Oat Squares)	0	0	0	0	0	0	1	Presweetened_Cereal
57327500	Cereal (Quaker Quisp)	1	1	1	1	1	1	0	Presweetened_Cereal
57328000	Quisp	0	0	0	0	0	0	1	Presweetened_Cereal
57328000	Cereal, raisin bran	1	1	1	1	1	1	0	Presweetened_Cereal
57329000	Raisin bran, NFS	0	0	0	0	0	0	1	Presweetened_Cereal
57329000	Cereal (Kellogg's Raisin Bran) Raisin Bran, Kellogg's	1	1	1	1	1	1	0	Presweetened_Cereal
57330000	Cereal (Kellogg's Raisin Bran) Raisin Bran, Kellogg's	0	0	0	0	0	0	1	Presweetened_Cereal
57330000	Cereal (Kellogg's Raisin Bran) Cereal (Kellogg's Raisin Bran Crunch)	1	0	0	0	0	0	0	Presweetened_Cereal
57330010	Raisin Bran Crunch, Kellogg's	0	0	0	0	0	0	1	Presweetened_Cereal
57330010	Cereal (Post Raisin Bran) Raisin Bran, Post	0	0	0	0	0	0	1	Presweetened_Cereal
57331000	Cereal (General Mills Total Raisin Bran)	1	1	1	1	1	1	0	Presweetened_Cereal
57332050	Raisin Bran, Total Cereal (General Mills Raisin Nut Bran)	1	1	1	1	1	1	0	Presweetened_Cereal
57332100	Raisin Nut Bran	0	0	0	0	0	0	1	Presweetened_Cereal
57332100		1	1	1	1	1	1	0	Presweetened_Cereal

57335500	Raisin Mini-Wheats, Kellogg's (formerly Raisin Squares Mini-Wheats; Raisin Squares)	1	1	0	0	0	0	0	Presweetened_Cereal
57335550	Cereal (General Mills Reese's Puffs)	0	0	0	0	0	0	1	Presweetened_Cereal
57335550	Reese's Peanut Butter Puffs cereal	1	1	1	1	1	1	0	Presweetened_Cereal
57336000	Cereal (General Mills Chex Rice)	0	0	0	0	0	0	1	Presweetened_Cereal
57336000	Rice Chex	1	1	1	1	1	1	0	Presweetened_Cereal
57337000	Cereal, rice flakes	0	0	0	0	0	0	1	Presweetened_Cereal
57337000	Rice Flakes, NFS	1	1	1	1	1	1	0	Presweetened_Cereal
57339000	Cereal (Kellogg's Rice Krispies)	0	0	0	0	0	0	1	Presweetened_Cereal
57339000	Rice Krispies	1	1	0	0	0	0	0	Presweetened_Cereal
57339000	Rice Krispies, Kellogg's	0	0	1	1	1	1	0	Presweetened_Cereal
57339100	Rice Krispies with Real Strawberries, Kellogg's	0	0	1	1	0	0	0	Presweetened_Cereal
57339500	Cereal (Kellogg's Rice Krispies Treats Cereal)	0	0	0	0	0	0	1	Presweetened_Cereal
57339500	Rice Krispies Treats Cereal (Kellogg's)	1	1	0	0	0	0	0	Presweetened_Cereal
57339500	Rice Krispies Treats Cereal, Kellogg's	0	0	1	1	1	1	0	Presweetened_Cereal
57340000	Cereal, puffed rice	0	0	0	0	0	0	1	Presweetened_Cereal
57340000	Rice, puffed	1	1	1	1	1	1	0	Presweetened_Cereal
57340700	Scooby Doo cereal, Kellogg's	0	1	0	0	0	0	0	Presweetened_Cereal
57340700	Scooby Doo Cinnamon Marshmallow Cereal, Kellogg's	1	0	0	0	0	0	0	Presweetened_Cereal
57341000	Cereal (Post Shredded Wheat 'n Bran)	0	0	0	0	0	0	1	Presweetened_Cereal
57341000	Shredded Wheat 'N Bran	1	1	1	1	1	1	0	Presweetened_Cereal
57341200	Cereal (Kellogg's Smart Start Strong)	0	0	0	0	0	0	1	Presweetened_Cereal
57341200	Smart Start Strong Heart	0	0	0	1	1	1	0	Presweetened_Cereal
57341200	Antioxidants Cereal, Kellogg's	1	1	1	0	0	0	0	Presweetened_Cereal
57342010	Smart Start, Kellogg's	0	1	1	1	1	0	0	Presweetened_Cereal
57344000	Smorz, Kellogg's	0	0	0	0	0	0	1	Presweetened_Cereal
57344000	Cereal (Kellogg's Special K)	1	1	1	1	1	1	0	Presweetened_Cereal
57344000	Special K	0	0	0	0	0	0	1	Presweetened_Cereal
57344001	Cereal (Kellogg's Special K Blueberry)	0	0	0	0	0	0	1	Presweetened_Cereal
57344001	Blueberry	0	0	0	0	1	1	0	Presweetened_Cereal
57344005	Special K Blueberry	0	0	0	0	0	0	1	Presweetened_Cereal
57344005	Cereal (Kellogg's Special K Chocolatey Delight)	0	0	0	0	0	0	1	Presweetened_Cereal
57344005	Chocolatey Delight	0	0	1	1	1	1	0	Presweetened_Cereal
57344007	Cereal (Kellogg's Special K Low Fat Granola)	0	0	0	0	0	0	1	Presweetened_Cereal
57344007	Low Fat Granola	0	0	0	0	1	1	0	Presweetened_Cereal
57344010	Special K Low Fat Granola	0	0	0	0	0	0	1	Presweetened_Cereal
57344010	Red Berries	0	0	0	0	0	0	1	Presweetened_Cereal
57344010	Special K Red Berries	0	1	1	1	1	1	0	Presweetened_Cereal
57344015	Cereal (Kellogg's Special K Fruit & Yogurt)	0	0	0	0	0	0	1	Presweetened_Cereal
57344015	Fruit & Yogurt	0	1	1	1	1	1	0	Presweetened_Cereal
57344020	Special K Fruit & Yogurt	0	0	0	0	0	0	1	Presweetened_Cereal
57344020	Cereal (Kellogg's Special K Vanilla Almond)	0	1	1	1	1	1	0	Presweetened_Cereal
57344025	Special K Vanilla Almond	0	0	0	0	0	0	1	Presweetened_Cereal
57344025	Cereal (Kellogg's Special K Cinnamon Pecan)	0	0	0	0	0	0	1	Presweetened_Cereal
57344025	Cinnamon Pecan, Kellogg's	0	0	0	1	1	1	0	Presweetened_Cereal
57346500	Oatmeal Honey Nut Heaven, Quaker (formerly Toasted Oatmeal, Honey Nut)	1	1	1	1	1	1	0	Presweetened_Cereal
57347000	Cereal (Kellogg's Corn Pops)	0	0	0	0	0	0	1	Presweetened_Cereal
57347000	Corn Pops	1	1	1	1	1	1	0	Presweetened_Cereal

57347500	Strawberry Squares Mini-Wheats, Kellogg's (formerly Strawberry Squares)	1	1	0	0	0	0	0	Presweetened_Cereal
57348000	Cereal, frosted corn flakes	0	0	0	0	0	0	1	Presweetened_Cereal
57348000	Frosted corn flakes, NFS Cereal (Kellogg's Frosted Flakes)	1	1	1	1	1	1	0	Presweetened_Cereal
57349000	Flakes	0	0	0	0	0	0	1	Presweetened_Cereal
57349000	Frosted Flakes, Kellogg	1	0	0	0	0	0	0	Presweetened_Cereal
57349000	Frosted Flakes, Kellogg's Cereal (Kellogg's Frosted Flakes, Reduced Sugar)	0	1	1	1	1	1	0	Presweetened_Cereal
57349020	Flakes, Reduced Sugar	0	0	0	0	0	0	1	Presweetened_Cereal
57349020	Frosted Flakes 1/3 Less Sugar, Kellogg's Reduced Sugar Frosted Flakes Cereal, Kellogg's	0	1	0	0	0	0	0	Presweetened_Cereal
57349020	Flakes Cereal, Kellogg's	0	0	1	1	1	1	0	Presweetened_Cereal
57355000	Cereal (Post Golden Crisp Golden Crisp (Formerly called Super Golden Crisp))	0	0	0	0	0	0	1	Presweetened_Cereal
57355000	Super Golden Crisp	1	1	1	1	1	1	0	Presweetened_Cereal
57401100	Cereal, toasted oat	0	0	0	0	0	0	1	Presweetened_Cereal
57401100	Toasted oat cereal	1	1	1	1	1	1	0	Presweetened_Cereal
57403100	Toasties, Post	1	1	1	1	1	1	0	Presweetened_Cereal
57404100	Malt-O-Meal Toasty D's Malt-O-Meal Apple and Cinnamon Toasty D's	1	1	1	1	0	0	0	Presweetened_Cereal
57406100	Cereal (General Mills Total)	0	0	0	0	0	0	1	Presweetened_Cereal
57406100	Total	1	1	1	1	1	1	0	Presweetened_Cereal
57406105	Total Cranberry Crunch	0	0	1	1	1	0	0	Presweetened_Cereal
57407100	Cereal (General Mills Trix)	0	0	0	0	0	0	1	Presweetened_Cereal
57407100	Trix Cereal (General Mills 25% Less Sugar Trix)	1	1	1	1	1	1	0	Presweetened_Cereal
57407110	Less Sugar Trix	0	0	0	0	0	0	1	Presweetened_Cereal
57407110	Trix, reduced sugar	0	0	1	1	1	1	0	Presweetened_Cereal
57408100	Cereal (Uncle Sam) Uncle Sam Cereal (formerly Uncle Sam's Hi Fiber Cereal)	0	1	1	1	1	1	0	Presweetened_Cereal
57408100	Uncle Sam's Hi Fiber Cereal	1	0	0	0	0	0	0	Presweetened_Cereal
57409100	Cereal (Post Waffle Crisp)	0	0	0	0	0	0	1	Presweetened_Cereal
57409100	Waffle Crisp, Post Cereal (Weetabix Whole Grain)	1	1	1	1	1	1	0	Presweetened_Cereal
57410000	Wheat Weetabix Whole Wheat Cereal	0	0	0	0	0	0	1	Presweetened_Cereal
57410000	Cereal (General Mills Chex Wheat)	1	1	1	1	1	1	0	Presweetened_Cereal
57411000	Wheat Chex	0	0	0	0	0	0	1	Presweetened_Cereal
57416000	Cereal, puffed wheat, plain	1	1	1	1	1	1	0	Presweetened_Cereal
57416000	Wheat, puffed, plain Cereal, puffed wheat, sweetened	0	0	0	0	0	0	1	Presweetened_Cereal
57416010	Wheat, puffed, presweetened with sugar	1	1	1	1	1	1	0	Presweetened_Cereal
57416010	Cereal (Post Shredded Wheat)	0	0	0	0	0	0	1	Presweetened_Cereal
57417000	Shredded Wheat, 100% Cereal (General Mills Wheaties)	1	1	1	1	1	1	0	Presweetened_Cereal
57418000	Wheaties	0	0	0	0	0	0	1	Presweetened_Cereal
57418000	Wheaties Cereal (General Mills Cheerios Yogurt Burst)	1	1	1	1	1	1	0	Presweetened_Cereal
57419000	Yogurt Burst Cheerios	0	0	0	0	0	0	1	Presweetened_Cereal
57419000	Yogurt Burst Cheerios	0	1	1	1	1	1	0	Presweetened_Cereal
57830100	Gerber Graduates Finger Snacks Cereal, baby food	0	0	0	0	0	0	1	Presweetened_Cereal
57830100	Gerber Graduates Finger Snacks Cereal, baby food	1	1	1	1	1	1	0	Presweetened_Cereal

EXHIBIT 1

Report of the Expert Panel

OPINION OF THE GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF ALLULOSE FOR USE IN FOOD

Introduction

An independent panel of experts (the GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by Tate & Lyle to determine the safety and Generally Recognized as Safe (GRAS) status of the use of allulose for use in select foods for human consumption. The allulose ingredient is proposed for use as a sweetener in alcoholic beverages, meat/poultry products, grain-based cereal bars, dried cranberries, and pre-sweetened cereals. The allulose ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature on the safety of allulose was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The GRAS Panel members independently reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on October 24, 2019 via teleconference. Based on their independent, critical evaluation of all of the available information and discussions during the October 24, 2019 teleconference, the GRAS Panel unanimously concluded that the intended uses described herein for Tate & Lyle's allulose ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Allulose for Use as an Ingredient in Human Food**) and manufactured according to cGMP, are safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

Allulose is a sweetener derived from corn (*Zea mays* L.) glucose by enzymatic epimerization. It contains negligible residual amounts of other related monosaccharides and impurities. Allulose has 70% of the sweetness of sucrose but provides negligible energy, and therefore is an excellent substitute for sucrose to reduce sugar and energy intake.

Manufacturing Process

The starting material is typical corn (U.S. Grade #2 Dent Corn [dried grain]), and the intermediate products are monosaccharides (glucose and fructose). All enzymes used in the process are safe and suitable for food uses and consistent with enzymes identified in previous GRAS notifications (including their sources). The allulose ingredient is produced in two forms: syrup and crystalline powder. The manufacturing process is conducted under Good Manufacturing Practice (GMP) for both end products and is identical in every step but the last.

Analytical results for the allulose ingredient confirm that the finished product meets the analytical specifications. The results also demonstrate that T&L's manufacturing process results in a consistently reproducible product and confirm the lack of significant levels of impurities and/or contaminants (e.g., heavy metals, microbiological contaminants). In addition, the corn starting material is periodically analyzed for the presence of pesticides and mycotoxins as part of Tate & Lyle's standard Quality Assurance processes. The results of stability testing conducted using liquid allulose, Dolcia Prima[®] LS brand, at temperatures of 4°C, 25°C, and 35°C demonstrate its stability through the end of the product's shelf-life in the syrup version up to 9 months. Stability studies on Dolcia Prima[®] DS crystalline allulose show that this material is stable for up to 30 months.

History of Use

Allulose is naturally present in small quantities in many common foods, such as in dried fruits (e.g., figs, raisins, fried dough, brown sugar and ketchup). Allulose has been added to food as an alternative sweetener and has a history of safe use. Multiple GRAS "no questions" letters have been issued (GRNs 400, 498, 693) regarding the safety of the intended uses and use levels of allulose in foods in which it serves as a sugar replacer/sweetener at levels up to 100% (FDA, 2012, 2014, 2017). Allulose is approved for addition to select foods as a sweetener, per previous GRAS notifications, and these foods include bakery products, chewing gum, hard candies, frozen dairy desserts, carbonated beverages, non-carbonated beverages, soft candies, yogurt, ready-to-eat cereals, coffee mix, jams/jellies, frostings, sauces, and many others.

Intended Use and Intake Assessment

The focus of this GRAS determination is for use of allulose as a sweetener in select foods that have not been previously identified in any of the publicly available GRN's (GRN 498 and GRN 693).

The following table summarizes these additional food categories and associated use levels. An intake assessment employing dietary survey data obtained from What We Eat in America (WWEIA), the dietary interview portion of the National Health and Nutrition Examination Survey (NHANES) was conducted to estimate the mean and 90th percentile daily intakes of allulose based on its intended use in foods.

Food Category	Maximum Use Level of Allulose (%)
Alcoholic beverages (e.g., premixed cocktails, wine coolers, and malt beverages) ^a	3.5
Meat/poultry (glazed meat and poultry (e.g., ham)) ^a	5
Meat/poultry (luncheon/formed deli meats) ^a	2
Meat/poultry (dried products such as jerky) ^a	15
Grain based cereal bars, protein bars ^b	25
Dried cranberries (i.e., Craisins) ^a	25
Condiments, major (ketchup and barbecue sauce) ^a	10
Cereal Bars ^a	25
Pre-sweetened breakfast cereal (>5% sugar) ^a	10

^a new food category; ^b new use level

The EDI for the extended uses of allulose in grams per day and grams per kilogram body weight per day for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older are presented below.

Estimated daily intake for allulose (g/day)

Food Category	Number of Users	Percent Users	EDI per User (g/day)		EDI per Capita (g/day)	
			Mean	90 th Percentile	Mean	90 th Percentile
US Population, Ages 2+						
Total*	36278	72.37%	3.75	8.25	2.71	7.05
US Population, Ages 2-5						
Total*	4081	88.09%	2.87	5.80	2.53	5.51
US Population, Ages 6-18						
Total*	11847	82.19%	3.88	8.21	3.20	7.57
US Population, Ages 19+						
Total*	20350	65.47%	3.80	8.50	2.60	7.05

* Total values reflect intake from foods in any of the proposed food categories

Estimated daily intake for allulose (g/kg bw/day)

Food Category	Number of Users	Percent Users	EDI per User (g/kg/day)		EDI per Capita (g/kg/day)	
			Mean	90 th Percentile	Mean	90 th Percentile
US Population, Ages 2+						
Total*	36278	72.37%	0.07	0.15	0.05	0.13
US Population, Ages 2-5						
Total*	4081	88.1%	0.17	0.34	0.15	0.32
US Population, Ages 6-18						
Total*	11847	82.2%	0.09	0.20	0.08	0.19
US Population, Ages 19+						
Total*	20350	65.5%	0.05	0.12	0.03	0.09

* Total values reflect intake from foods in any of the proposed food categories.

The population group *per user* 90th percentile intakes ranged from 5.8 to 8.5 g/day, with the highest overall *per user* 90th percentile intake being in the 19+ age group and the lowest in the 2- to 5-year age group. The population group *per user* 90th percentile intakes normalized for body weight ranged from 0.12 to 0.34 g/kg bw/day, with the highest overall *per user* 90th percentile intake being in the 2- to 5-year age group and the lowest in the 19+ age group. Compared to intake assessments in previous GRAS notifications, the addition of allulose to the new food categories represents an intake of 5.8–8.5 g/day by a 90th percentile intake allulose consumer. Given a previously estimated daily intake of approximately 30 g/day (e.g., GRN 693), the cumulative estimated daily intake (CEDI) is approximately 35.8–38.5 g/day when considering extended uses of allulose proposed in this notification.

The estimate of the 90th percentile *per user* consumption for the general US population (2+ years of age) of approximately 8.25 g/day, or 0.15 g/kg bw/day and the CEDI are extremely conservative. In reality, the actual consumption would be much less, because the intake assessment assumes that individuals consume all the listed foods daily, and in some cases, the allulose would be present in only a subcomponent of an identified food.

Safety Data

Allulose has been added to food as an alternative sweetener and has a history of safe use. Multiple GRAS “no questions” letters have been issued (GRNs 400, 498, 693) with respect to the conclusion regarding the safety of the intended uses and use levels of allulose in foods in which it serves as a sugar replacer/sweetener at levels up to 100% (FDA, 2012, 2014, 2017). Clinical and preclinical studies with allulose have been conducted to examine its general toxicity and gastrointestinal tolerance.

Regulatory authorities have reviewed the safety of allulose and found it to be safe for use in human food. Numerous studies and publications support the safety of allulose, including *in vitro* studies, *in vivo* animal studies, and clinical studies in humans. A summary of the most relevant studies on allulose ADME, acute and subchronic toxicity, reproductive and developmental toxicity, mutagenicity and genotoxicity, and chronic toxicity in animals along with clinical studies have been summarized and reviewed. The compositional profile of allulose presents no obvious safety concerns. As a result, allulose has been reviewed and approved in several countries for addition to food for human consumption.

ADME data on allulose are available in both animals and humans, and the data are similar for both. Allulose is rapidly absorbed such that large bolus doses are more likely to have an impact on laxation than smaller cumulative doses. As such, clinical studies have demonstrated that the tolerability of allulose is highly dependent on the mode and timeline of ingestion. Individual tolerance develops with continued ingestion over time. Mild GI intolerance is considered to be a physiological response to osmotic loading of no toxicological significance, is generally self-limiting, and not severe or indicative of toxicity per se but is a short-term individual tolerability issue similar to other foods (dried fruit) or food ingredients (fructose), and other sweeteners such as polyols like sorbitol, mannitol, and xylitol.

No adverse effects attributable to allulose were observed in multiple animal studies; in a 90-day study (2000 mg/kg bw/day) and in a chronic study (approximately 1300 mg/kg bw/day).

Data are available from a number of human studies in both sexes, healthy individuals, and sensitive subpopulations such as diabetics. No effects were observed in multiple human studies, except gastrointestinal intolerance at very high dose levels. Gastrointestinal intolerance is related to the presence of excess indigestible material in the gastrointestinal tract and is temporary and reversible. It is not unique to allulose; similar effects are observed with other sweeteners, such as polyols like sorbitol, mannitol, and xylitol.

Allulose can be considered safe for human consumption at up to 63 g/day, when consumed in portions throughout the day as one would typically, based on multiple meals or snacks throughout the day (Han et al., 2018), and up to 28–42 g (0.4 – 0.6 g/kg/day for a 70 kg individual) can be consumed in one sitting (Han et al., 2018; Iida et al., 2007).

In summary, the published study data, additional unpublished supporting data, and previous reviews by regulatory authorities (e.g., GRN Nos. 400, 498, 693), support the conclusion that Tate & Lyle's allulose ingredient is safe for use as a sweetener, at the proposed use levels foods.

General Recognition of the Safety of Allulose

The intended use of allulose has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called “technical” element of the GRAS determination and is based on the following:

- Allulose is manufactured from corn, following current cGMP for food (21 CFR § Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food. The allulose ingredient has been characterized appropriately, contains a minimum of 95%–98% allulose (syrup and crystalline forms, respectively), and meets appropriate food-grade specifications.
- There is a body of common knowledge of historical human consumption of allulose from foods containing allulose. Allulose is naturally present in small quantities in many common foods, such as in dried fruits (e.g., figs, raisins, dried dough, brown sugar, and ketchup). The additional intended uses will be in alcoholic beverages, meat/poultry products, grain-based cereal bars, dried cranberries, and presweetened cereal as a sweetener.
- Allulose is currently added to food, and multiple GRAS “no-questions” letters have been issued (GRNs 400, 498, 693) that support the safe use of allulose in foods in which it serves as a sugar replacement/sweetener .
- The proposed uses result in a total population group *per user* 90th percentile intake range of 5.8-8.5 g/day, with the highest overall *per user* 90th percentile intake being in the 19+ age group and the lowest in the 2- to 5-year age group. The population group *per user* 90th percentile intakes normalized for body weight ranged from 0.12 to 0.34 g/kg bw/day, with the highest overall *per user* 90th percentile intake being in the 2- to 5-year age group and the lowest in the 19+ age group.
- Compared to intake assessments in previous GRAS notifications, the addition of allulose to the new food categories represents an intake of approximately 6 – 8.5 g/day by a 90th percentile allulose intake consumer. Given a previously estimated daily intake of approximately 30 g/day (e.g., GRN 693), the cumulative estimated daily intake (CEDI) is approximately 35.8 - 38.5 g/day.
- Allulose can be considered safe for human consumption at up to 63 g/day, when consumed in portions throughout the day as one would typically, based on multiple meals or snacks throughout the day. and up to 28–42 g (0.4 – 0.6 g/kg/day for a 70 kg individual) can be consumed in one.
- No safety/toxicity concerns related to consumption of allulose are evident, beyond that of gastrointestinal intolerance at high bolus doses.

- Regulatory authorities have reviewed the extensive safety study database for allulose and found no issues of concern with respect to its use in human food at the proposed use levels. Numerous studies have been conducted and published in support of the safety of allulose, including *in vitro* studies and *in vivo* animal studies (i.e., acute and subchronic toxicity, mutagenicity and genotoxicity, chronic toxicity), as well as clinical studies in adults.
- The body of publicly available scientific literature on the consumption and safety of allulose is sufficient to support the safety and GRAS status of the proposed new uses of the allulose ingredient.

Conclusions of the Expert Panel

We, the undersigned independent qualified members of the GRAS Panel, have individually and collectively, critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's allulose ingredient. We unanimously conclude that the intended use of the allulose ingredient produced consistent with good manufacturing practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier [**"GRAS Determination of Allulose for Use as an Ingredient in Human Food"**] is safe.

We the members of the GRAS Panel, further unanimously conclude that the intended use of Tate & Lyle's allulose ingredient, produced consistent with good manufacturing practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods and alcoholic beverages specified herein.

It is our professional opinion that other qualified experts critically evaluating the same information, would concur with this conclusion.



Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Nov 8, 2019
Date

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Consultant
Tarka Group, Inc.

Date

Thomas Vollmuth, Ph.D.
Consultant
Vollmuth and Associates, LLC

Date

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Michael Carakostas, DVM, PhD
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Conclusions of the Expert Panel

We, the undersigned independent qualified members of the GRAS Panel, have individually and collectively, critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Tate & Lyle's allulose ingredient. We unanimously conclude that the intended use of the allulose ingredient produced consistent with good manufacturing practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier [**GRAS Determination of Allulose for Use as an Ingredient in Human Food**] is safe.

We the members of the GRAS Panel, further unanimously conclude that the intended use of Tate & Lyle's allulose ingredient, produced consistent with good manufacturing practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in conventional foods and alcoholic beverages specified herein

It is our professional opinion that other qualified experts critically evaluating the same information, would concur with this conclusion.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Date

Stanley M. Tarka, Jr., Ph.D., F.A.T.S.
Consultant
Tarka Group, Inc.

Date

Thomas Vollmuth, Ph.D.
Consultant
Vollmuth and Associates, LLC

Date

11/11/2019

References

FDA. 2012. GRAS Notification No. 400. D-psicose.

<http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=400>.

FDA. 2014. GRAS Notification No. 498. D-psicose.

<http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=498>.

FDA 2017. GRAS Notification No. 693

<http://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=693>.

Han Y, Choi BR, Kim SY. 2018. Gastrointestinal tolerance of d-allulose in healthy and young adults. a non-randomized controlled trial. *Nutrition* 10(12), 2010-2021.

Iida T, Kishimoto Y, Yoshikawa Y, Okuma K, Yagi K, Matsuo T, Izumori K. 2007. Estimation of maximum non-effective level of D-psicose in causing diarrhea in human subjects. *J Advanced Food Ingred* 10(1):15–19.

Twelve pages of confidential information removed.

From: [Don Schmitt](#)
To: [Hice, Stephanie](#)
Subject: Re: GRN 000893 - Questions for Notifier
Date: Sunday, March 29, 2020 9:27:31 AM
Attachments: [image003.png](#)
[Final FDA Answers 032620.pdf](#)

Hello Dr. Hice.

Please find attached Tate & Lyle's responses to your questions regarding GRN 893.

Regards,

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

ToxStrategies, Inc.

739 Thornapple Drive

Naperville, IL 60540

phone: 630.352.0303

email: dschmitt@toxstrategies.com



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From: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>

Date: Friday, March 13, 2020 at 12:05 PM

To: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>

Subject: Re: GRN 000893 - Questions for Notifier

Thank you, Dr. Hice.

We will respond within the 10 day period.

Don

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

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From: "Hice, Stephanie" <Stephanie.Hice@fda.hhs.gov>
Date: Friday, March 13, 2020 at 11:56 AM
To: "Donald Schmitt, MPH" <dschmitt@toxstrategies.com>
Subject: GRN 000893 - Questions for Notifier

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

Dear Mr. Schmitt,

During our review of GRAS Notice No. 000893, we noted further questions that need to be addressed and are attached to this email.

We respectfully request a response within **10 business days**. If you are unable to complete the response within that time frame, please contact me to discuss further options. Please do not include any confidential information in your responses.

If you have questions or need further clarification, please feel free to contact me. Thank you in advance for your attention to our comments.

Sincerely,

Stephanie Hice

Stephanie Hice, PhD

Staff Fellow (Biologist)

Division of Food Ingredients

Center for Food Safety and Applied Nutrition

Office of Food Additive Safety

U.S. Food and Drug Administration

stephanie.hice@fda.hhs.gov



Responses to Questions/Comments Regarding GRN 000893:

Question 1. On pages 4 and 41, the notifier lists the citation for “Part 7, Supporting Data and Information” as 21 CFR 170.250. The appropriate citation is 21 CFR 170.255. Please provide a statement that corrects this reference.

Response: The appropriate citation for Part 7 is 21 CFR 170.255, not 170.250.

Question 2. On page 6, the notifier states that the intended use of allulose is GRAS based on scientific procedures as defined by 21 CFR 570.30(a)(b). The appropriate citation is 21 CFR 170.30(a)(b). Please provide a statement that corrects this reference.

Response: The appropriate reference is 21 CFR 170.20(a)(b), not 21 CFR 570.30(a)(b).

Question 3. The notifier states that the enzyme D-psicose 3-epimerase is used to epimerize fructose to allulose. Please indicate if this enzyme is purchased or if it is prepared by the notifier. In addition, please indicate if this enzyme is removed from the final product or if it is expected to be present in the final product. We note that this enzyme has not been evaluated by FDA. We recommend that you submit a GRAS notice for the intended use of the enzyme.

Response: The epimerase enzyme is purchased from CODEXIS. The enzyme never comingles with the final product but it’s possible presence in the allulose product is evaluated (see attached analytical results for the presence of epimerase enzyme in allulose product and the ELISA analytical method employed). The epimerase enzyme was self-determined as GRAS in 2014. The conclusion and signature page of the GRAS Panel that evaluated the safety and GRAS status (based on scientific procedures) of the epimerase enzyme is also attached.

Question 4. In Table 4, the provided specifications for yeasts and molds in crystalline allulose are listed as <10 CFU/10 grams (page 13); however, in Table 6, results from Lot No. LO19F90351 are 10 CFU/10 grams (page 14). Please clarify whether the provided specifications for yeasts and molds in crystalline allulose are <10 CFU/10 grams.

Response: The specification for yeast and molds is ≤ 10 CFU/10 grams. New Tables 4 - 6 along with revised COAs have been attached to this document and reflect the correct specification of ≤ 10 CFU/10 grams.

Question 5. On page 14, Table 7 is titled “Other microbiological criteria for three non-consecutive lots of liquid syrup and crystalline allulose”; however, the table includes the heading “Heavy metal limit”. Please provide a revised table with the correct title.

Response: See the following revised table.

Table 7. Other microbiological criteria for three non-consecutive lots of liquid syrup and crystalline allulose

Microbiological Criteria				
Allulose Syrup		Lot No. YP19DO3774	Lot No. YP19G01863	Lot No. YP18D03177
<i>E. coli</i> (cfu/10g)	ND	ND	ND	ND
<i>Salmonella</i> (cfu/25g)	Negative	Negative	Negative	Negative
Crystalline Allulose		Lot No. LO18J90596	Lot No. LO19F90351	Lot No. LO18J90294
<i>E. coli</i> (cfu/10g)	ND	ND	ND	ND
<i>Salmonella</i> (cfu/25g)	Negative	Negative	Negative	Negative

ND = not detected; Limits of detection are 1 CFU/10g for *E. coli* and 1 CFU/25g for *Salmonella*, respectively.

Question 6. The notifier should indicate that all analytical methods used to analyze the batches for conformance with the stated specifications have been validated for that particular purpose.

Response: All analytical methods used to analyze batches of allulose against its specifications have been validated for that purpose.

Question 7. The notifier provides four methods for the analysis for arsenic (see below). We note that some of these methods are not appropriate for the analysis for arsenic. Please indicate the actual method used for the arsenic analysis and provide a statement that it is validated for that purpose.

A. AOAC 993.14 (Appendix B), which corresponds to detection of trace elements in waters and wastewaters.

B. AOAC 984.27 (Appendix B), which corresponds to detection of calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc in infant formula.

C. AOAC 985.01 (Appendix B), which corresponds to detection of metals and other elements in plants and pet foods.

D. AOAC 2011.14 (Appendix B), which corresponds to detection of calcium, copper, iron, magnesium, manganese, potassium, phosphorous, sodium and zinc in fortified food products.

Response: The method employed for the analysis of arsenic is a validated internal Tate & Lyle method designated as R method 2837 and is based upon AOAC 2011.19 and AOAC 993.14 (modified). The attached COAs have been corrected as such.

Question 8. The notifier provides three methods for the analysis for cadmium (see below). We note that some of these methods are not appropriate for the analysis for cadmium. Please indicate the method used for the cadmium analysis and provide a statement that it is validated for that purpose.

A. AOAC 984.27 (Appendix B), which corresponds to detection of calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc in infant formula.

B. AOAC 985.01 (Appendix B), which corresponds to detection of metals and other elements in plants and pet foods.

C. AOAC 2011.14 (Appendix B), which corresponds to detection of calcium, copper, iron, magnesium, manganese, potassium, phosphorous, sodium and zinc in fortified food products.

Response: The method employed for the analysis of cadmium is a validated internal Tate & Lyle method designated as R method 2837 and is based upon AOAC 2011.19 and AOAC 993.14 (modified). The attached COAs have been corrected as such.

Question 9. The notifier states that the method used to detect mercury is AOAC 993.14 (Appendix B), which corresponds to detection of trace elements in waters and wastewaters. Please clarify if this method is appropriate and validated for the analysis of mercury in food.

Response: The method employed for the analysis of mercury is a validated internal Tate & Lyle method designated as R method 2832 and is based upon AOAC 2011.19 and AOAC 993.14 (modified). The attached COAs have been corrected as such.

Question 10. The notifier states that the specification for detection of *E. coli* is ISO 21528-1:2004 and MSZ ISO 21528-2:2007 (Appendix B). We note that this standard has been revised by ISO 21528-1:2017. It is not clear why a method was listed as a specification for *E. coli*. We further note that a different method (TN 10512L) was listed for the analysis for *E. coli*. It is not clear if this is an internal method or a standard method. Please clarify the specification for *E. coli*, provide the method used for the analysis for *E. coli*, and indicate if the method is validated for the intended use.

Response: The methods listed in the COAs as a specification for *E. coli* was a mistake. The method employed was TN10512L, an internal method, which references ISO21528-1:2017. The method TN10512L is validated for the intended use. A copy of the analytical procedure can be provided as necessary.

Question 11. The notifier states that the specification for detection of *Salmonella* is MSZ-EN ISO 6579:2006 (Appendix B). We note that this standard has been revised by ISO 6579-1:2017. It is not clear why a method was listed as a specification for *Salmonella*. We further note that a different method (TN 10547) was listed for the analysis for *Salmonella*. It is not clear if this is an internal method or a standard method. Please clarify the specification for *Salmonella*, provide the method used for the analysis for *Salmonella*, and indicate if the method is validated for the intended use.

Response: The method listed in the COAs as a specification for *Salmonella* was a mistake. The method employed was TN10547, an internal validated method for the intended use, and references ISO6579-1:2017. A copy of the analytical procedure can be provided as necessary.

Question 12. In Appendix B, the specification for cadmium in the liquid syrup and crystalline allulose is listed as <1 ppm; however, in Table 4, the specification is listed as <0.1 ppm (page 13). Please clarify whether the specification for cadmium in the liquid syrup and crystalline allulose is <0.1 ppm or <1 ppm.

Response: The correct specification for cadmium in the liquid syrup and crystalline allulose is <0.1 ppm.

Question 13. Based on the toxicology and human tolerance studies, the maximum tolerated consumed allulose level in humans has been reported to be between 28 g/p/d and 33.3 g/p/d. Therefore, the true tolerable level of consumed allulose will fall somewhere in this range. The current 90th percentile cumulative exposure for allulose is estimated to be 30 g/p/d (GRNs 000828 and 000693). The maximum cumulative exposure presented in your GRAS notice is 38.5 g/p/d. Therefore, the proposed uses are not supported by the available safety and tolerance data. We note that in order to derive your cumulative exposure, the 90th percentile exposure from GRN 000693 was added to the 90th percentile exposure from the proposed use, which is not appropriate to estimate a cumulative exposure as the population that is the 90th percentile consumer of the current uses is not the same population that is the 90th percentile consumers of the proposed uses. Please review the proposed uses, the use levels, and consider revising the cumulative exposure using appropriate methodology to ensure that the proposed use is supported by the safety and tolerance data.

Response: We agree that it was not appropriate to estimate the cumulative exposure as presented and agree that the population that is the 90th percentile consumer of the current uses is not the same population that is the 90th percentile consumers of the proposed uses. As conducted and presented, the cumulative exposure estimate of 38.5 g/day is likely an overestimate of the cumulative estimated daily intake (CEDI) and would most likely represent a minimal increase above 30 g/day. Rather than conduct a new intake assessment at this time, we believe that the human study data presented in GRN 893 and discussed below support a slight increase in the CEDI.

Han et al. (2018) investigated gastrointestinal tolerance in 30 healthy adults (15 males and 15 females), ages 21–30 years old. Two experiments were conducted. In the first experiment, the study participants were given daily single doses of allulose starting at 0.1 g/kg bw/day and increasing by 0.1 g/kg bw/day every week until gastrointestinal symptoms were observed, at which time the study was terminated. In the fifth week, some participants developed gastrointestinal symptoms, and the study was stopped. The maximum tolerated dose in this study was 0.4 g/kg bw/day (when all of the allulose was consumed as a single dose). This maximum tolerated single dose was then used by Han et al. (2018) to conduct a second study in which the same protocol was followed as the first study, with the difference that, this time, the allulose was consumed in portions throughout the day, similar to how meals and snacks are consumed by people. In this case, the maximum tolerated dose was 0.9 g/kg bw/day, or about 63 g/day for a 70-kg adult.

The clinical study of Iida et al. (2007) established a dose-response relationship for the onset of diarrhea in humans, showing that in men the maximum tolerated dose was 0.5 g/kg bw, whereas in women, it was 0.6 g/kg bw (above these doses, gastrointestinal effects such as abdominal pain, gas formation, and diarrhea occurred). Thus, it was established that, for humans, the NOAEL for allulose is 0.5 g/kg bw (33.3 g/day) for men and 0.6 g/kg bw (31 g/day) for women (Iida et al., 2007; FDA, 2012, 2014, 2017). It is noteworthy that these no-effect levels for human subjects from Iida et al. (2007) are based on **single doses** of allulose, where the daily dose was consumed completely in one sitting. The actual threshold is even higher if the allulose was consumed in portions throughout the day, as one would when consuming meals and snacks daily (Han et al.,

2018).

Numerous other clinical studies have been conducted with allulose. No safety/toxicity concerns related to consumption of allulose are evident, beyond that of gastrointestinal intolerance at high bolus doses, not divided doses or portions throughout the day. In addition, no adverse effects attributable to allulose were observed in multiple animal studies; e.g., in a 90-day study (2000 mg/kg bw/day) and in a chronic study (approximately 1300 mg/kg bw/day).

The CEDI is a conservative estimate of allulose intake by consumers. It assumes that allulose will be used *at the maximum levels allowed* in *all* foods within *all* product categories and the maximum amounts of these foods will be consumed daily by consumers for a long period of time. In reality, the intake is expected to be much lower than this. Therefore, there is already a built-in safety margin within the cumulative intake assessment.

We believe that the clinical study data described above support a conclusion that allulose can be considered safe for human consumption at up to 63 g/day, when consumed in portions throughout the day as one would typically, based on multiple meals or snacks throughout the day and up to 28–42 g (0.4 – 0.6 g/kg/day for a 70 kg individual) can be consumed in one sitting. The proposed new uses would not result in consumption of allulose near 42 g/day or 63 g/day supported by the clinical studies of Han et al. (2018) and Iida et al. (2007).

Table 4. Specifications for allulose

Parameter	Liquid Syrup	Crystalline Granules
Appearance	Colorless to slightly yellow	Off white
Allulose (% dry basis)	>95	>99.1
Total non-allulose saccharides (%)	<5	<2
Dry solids (%)	70-78	n/a
Moisture (%)	n/a	<1
pH	3.0 – 4.5	n/a
Ash (%)	n/a	<0.5
SO ₂ (ppm)	<10	<10
Total plate count (cfu/10g)	<200	<200
Yeast (cfu/10g)	≤10	≤10
Mold (cfu/10g)	≤10	≤10
Arsenic (ppm)	<0.1	<0.1
Cadmium (ppm)	<0.1	<0.1
Lead (ppm)	<0.1	<0.1
Mercury (ppm)	<0.01	<0.01

n/a = not applicable

Table 5. Analytical results for three non-consecutive lots of allulose syrup

Specification		Lot No. YP19DO3774	Lot No. YP19G01863	Lot No. YP18D03177
Allulose (% dry basis)	>95	96.2	96.3	96.3
Total non-allulose saccharides (%)	<5	2.6	2.9	2.4
Dry solids (%)	70-78	70.8	70.5	71.0
pH	3.0 – 4.5	4.2	3.9	4.3
Sulfur dioxide (ppm)	<10	<10	<10	<10
Total plate count (cfu/10g)	<200	<10	<10	<10
Yeast (cfu/10g)	≤10	<10	<10	<10
Mold (cfu/10g)	≤10	<10	<10	<10
Arsenic (ppm)	<0.1	0.016	0.011	0.024
Cadmium (ppm)	<0.1	0.006	<0.005	0.006
Lead (ppm)	<0.1	<0.005	<0.005	0.006
Mercury (ppm)	<0.01	<0.005	<0.005	<0.005

Table 6. Analytical results for three non-consecutive lots of crystalline allulose

Specification		Lot No. LO18J90596	Lot No. LO19F90351	Lot No. LO18J90294
Allulose (% dry basis)	>99.1	99.4	99.8	99.2
Total non-allulose saccharides (%)	<2	0.27	0.06	0.29
Moisture (%)	<1	0.14	0.12	0.10
Ash (%)	<0.5	<0.1	<0.1	<0.1
Sulfur dioxide (ppm)	<10	<10	<10	<10
Total plate count (cfu/10g)	<200	<10	10	10
Yeast (cfu/10g)	≤10	<10	10	<10
Mold (cfu/10g)	≤10	<10	10	<10
Arsenic (ppm)	<0.1	<0.005	<0.005	<0.005
Cadmium (ppm)	<0.1	<0.005	<0.005	<0.005
Lead (ppm)	<0.1	<0.005	<0.005	<0.005
Mercury (ppm)	<0.01	<0.005	<0.005	<0.005

Question 3 Attachments

GRAS PANEL ENZYME CDX-032 EPIMERASE
August 29, 2014

Conclusion

We, the members of the Expert Panel, have independently and collectively critically evaluated the information summarized above and conclude that Codexis' CDX-032 D-psicose-3-epimerase enzyme preparation produced by fermentation from recombinant *Escherichia coli* expressing an engineered synthetic epimerase gene, meeting appropriate food-grade specifications and manufactured in accordance with current Good Manufacturing Practice, is safe, suitable, and Generally Recognized as Safe (GRAS) (based on scientific procedures) for its intended use in the production of D-psicose.

It is our opinion that other qualified experts would concur with these conclusions.

[Redacted Signature]

Stanley M. Tarka Ph.D.
The Pennsylvania State University College of Medicine

29 August 2014

Date

[Redacted Signature]

Michael W. Pariza Ph.D.
Emeritus Professor, Food Science
Emeritus Director, Food Research Institute
University of Wisconsin

29 Aug 2014

Date

[Redacted Signature]

Ashley Roberts Ph.D.
Intertek Health Sciences Consultancy

29 August 2014

Date

Revised Certificates of Analysis

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	NA

Analytical Data

Sample Number: Dolcia Prima LS YP19D03774

Manufacture Date May 6, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Off white	Visual inspection
Allulose	% dsb	96.2	≥95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.6	≤5%	Saccharide distribution – TN67435
pH		4.2	3.0-4.5	pH – TN60710
Dry solids	%	70.8	70% to 78%	DS R I M – TN27501
Total plate count	CFU/10 g	<10	≤200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	None detected	E. coli – TN 10512L
Salmonella	CFU/ 25 g	Negative	Negative	<i>Salmonella</i> – TN 10547
Yeast	CFU/10 g	<10	≤10 CFU/10 g	Mold & Yeast – TN10600
Mold	CFU/10 g	<10	≤10 CFU/10 g	Mold & Yeast – TN10600
SO ₂	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	15.8	<0.10 ppm	Elemental Analysis of Heavy Metals - R 2837
Lead	ppb	5.6	<0.10 ppm	Elemental Analysis of Heavy Metals - R 2837
Cadmium	ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832



Shana Bender – Manager Analytical

3/25/2020

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima LS YP19G01863

Manufacture Date: April 27, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Colourless to slightly yellow	Visual inspection
Allulose	% dsb	96.34	≥95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.87	≤5%	Saccharide distribution – TN67434
pH	%	3.9	3.0-4.5	pH – TN60710
Dry solids	%	70.5	70% to 78%	DS RI – TN27501
Total plate count	CFU/10 g	<10	≤200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	None detected	<i>E. coli</i> TN 10512L
Salmonella	CFU/ 25 g	Negative	negative	<i>Salmonella</i> – TN 10547
Yeast	CFU/10 g	<10	≤10 CFU/10 g	Mold & Yeast – TN10600
Mold	CFU/10 g	<10	≤10 CFU/10 g	Mold&Yeast – TN10600
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	11.4	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Lead	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Cadmium	ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832



Shana Bender – Manager Analytical

3/25/2020

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima LS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima LS YP18D03177

Manufacture Date April 13, 2018

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Colourless to slightly yellow	Visual inspection
Allulose	% dsb	96.3	≤95%	Saccharide distribution – TN67435
Total non allulose saccharides	% dsb	2.4	≤5%	Saccharide distribution – TN67435
pH		4.3	3.0-4.5	pH – TN60710
Dry solids	%	71	70% to 78%	DS RI – TN27501
Total plate count	CFU/10 g	<10	≤200 CFU/10 g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	None detected	E. Coli - TN 10512L
Salmonella	CFU/ 25 g	Negative	Negative	Salmonella – TN 10547
Yeast	CFU/10 g	<10	≤10 CFU/10 g	Mold & Yeast – TN10600
Mold	CFU/10 g	<10	≤10 CFU/10 g	Mold & Yeast – TN10600
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	23.8	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Lead	ppb	6	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Cadmium	ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832



Shana Bender – Manager Analytical

3/25/2020

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

Product: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to:	Date Shipped: N.A

Analytical Data

Sample Number: Dolcia Prima DS LO18J90596

Manufacture Date November 15, 2018

Analysis	Unit	Result	Specification	Methods
Color	n/a	Off white	Off white	Visual inspection
Screen	%	0.1	<5%	
screen	%	7	<10%	
Allulose	% dsb	99.35	≥99.10%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.27	≤0.90%	Saccharide distribution – TN67435
moisture	%dsb	0.14	≤0.50%	Moisture – TN46040
Ash	% dsb	<0.1%	<0.5%	Ash – TN 09580
Total plate count	CFU/g	<10	≤200 CFU/g	Total Plate Count – TN10565
E. Coli.	CFU/ g	None detected	None detected	<i>E. coli</i> – TN 10412L
Salmonella	CFU/ 25 g	Negative	Negative	<i>Salmonella</i> TN 10510
Yeast	CFU/ g	<10	≤10 CFU/g	Mold & Yeast – TN47010
Mold	CFU/10 g	<10	≤10 CFU/g	Mold & Yeast – TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals – R method 2837
Lead	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Cadmium	ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832

3/25/2020

Shana Bender – Manager Analytical

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

PRODUCT: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima DS LO19F90351

Manufacture Date: June 3, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Off white	Off white	Visual inspection
Screen	# 10	0.1	<5%	
screen	# 200	3	<10%	
Allulose	% dsb	99.74	≥99.1%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.06	≤0.9%	Saccharide distribution – TN67434
moisture	%dsb	0.12	≤0.5%	Moisture – TN46040
Ash	% dsb	<0.1%	<0.5%	Ash – TN 09580
Total plate count	CFU/ g	10	≤200 CFU/g	Total Plate Count – TN10565; TN10560
E. Coli.	CFU/10 g	None detected	None detected	<i>E. Coli</i> TN10512L
Salmonella	CFU/ 25 g	Negative	Negative	<i>Salmonella</i> TN 10547
Yeast	CFU/g	10	≤10 CFU/ g	Mold & Yeast – TN47010
Mold	CFU/10 g	10	≤10 CFU/ g	Mold & Yeast – TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals – R method 2837
Lead	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Cadmium	ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832

3/25/2020

Shana Bender – Manager Analytical

Date

TATE & LYLE

CONSISTENTLY FIRST IN RENEWABLE INGREDIENTS
ICD CERTIFICATE OF ANALYSIS

Product: Dolcia Prima DS	PO# : N.A
Report Date: 09/22/2019	Order # : NA
Sent to: N.A	Date Shipped:
Contact: N.A	N.A

Analytical Data

Sample Number: Dolcia Prima DS LO18J90294

Manufacture Date October 3, 2019

Analysis	Unit	Result	Specification	Methods
Color	n/a	Colorless	Off white	Visual inspection
Screen US#10	%	0.1	<5%	
Screen US #200	%	6.6	<10%	
Allulose	% dsb	99.19	≥99.1%	Saccharide distribution – TN67450
Total non allulose saccharides	% dsb	0.29	<0.9%	Saccharide distribution – TN67435
moisture	%dsb	0.1	≤0.5%	Moisture – TN46040
Ash	% dsb	<0.1%	<0.5%	Ash – TN 09580
Total plate count	CFU/g	10	≤200 CFU/g	Total Plate Count –TN10560
<i>E. Coli.</i>	CFU/g	None detected	None detected	<i>E. Coli</i> - TN10512
<i>Salmonella</i>	CFU/ g	Negative	Negative	<i>Salmonella</i> TN 10547
Yeast	CFU/g	<10	≤10 CFU/g	Mold & Yeast – TN47010
Mold	CFU/g	<10	≤10 CFU/g	Mold & Yeast – TN47010
SO2	ppm	<10	<10 ppm	Sulphur dioxide – TN80055
Arsenic	ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals – R method 2837
Lead	Ppb	<5	<0.10 ppm	Elemental Analysis of Heavy Metals - R method 2837
Cadmium	Ppb	<5	<0.1 ppm	Elemental Analysis of Heavy Metals – R method 2837
Mercury	ppb	<5	<0.01 ppm	Elemental Analysis of Mercury - R method 2832

3/25/2020

Shana Bender – Manager Analytical

Date