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SENT *VIA* FEDEX

October 8, 2010

Robert L. Martin, Ph.D.
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notice for Cyclic Dextrin, Highly Branched

Dear Dr. Martin:

In accordance with proposed 21 CFR §170.36 [Notice of a claim for exemption based on a Generally Recognized As Safe (GRAS) determination] published in the *Federal Register* [62 FR 18938 (17 April 1997)], I am submitting in triplicate, as the notifier (Ezaki Glico Co., Ltd., 4-6-5, Utajima, Nishioyogogawa, Osaka, Japan], a Notice of the determination, on the basis of scientific procedures, that Ezaki Glico's cyclic dextrin, highly branched, as defined in the enclosed documents, is GRAS under specific conditions of use as a food ingredient, and therefore, is exempt from the premarket approval requirements of the *Federal, Food, Drug and Cosmetic Act*. Information setting forth the basis for the GRAS determination, which includes a comprehensive summary of the data available and reviewed by an independent panel of experts in support of the safety of cyclic dextrin, highly branched under the intended conditions of use, also are enclosed.

I trust that the enclosed Notice is acceptable. Should you have any questions or concerns regarding this GRAS Notice, please do not hesitate to contact me at any point during the review process so that we may provide a response in a timely manner.

Sincerely,

(b) (6)

Takashi Kuriki
Chief Scientific Officer

Encl.

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GRAS Exemption Claim for Cyclic Dextrin, Highly Branched

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

Submitted by: Ezaki Glico Co., Ltd
4-6-5, Utajima, Nishioyogogawa
Osaka, Japan

October 7, 2010

GRAS Exemption Claim for Cyclic Dextrin, Highly Branched

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GRAS Exemption Claim for Cyclic Dextrin, Highly Branched

I GRAS Exemption Claim

I.A Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)] (U.S. FDA, 1997)

Cyclic dextrin, highly branched has been determined to be Generally Recognized as Safe (GRAS) by Ezaki Glico Co., Ltd. (Ezaki) for use in a variety of traditional food products, consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act.* This determination is based on scientific procedures as described in the following sections. Therefore, the use of cyclic dextrin, highly branched in food as described below is exempt from the requirement of premarket approval.

Signed,

(b) (6)

October 19, 2010
Date

Takashi Kuriki
Chief Scientific Officer
Ezaki Glico Co., Ltd
4-6-5, Utajima, Nishioyogogawa
Osaka, Japan

I.B Name and Address of Notifier

Takashi Kuriki
Chief Scientific Officer
Ezaki Glico Co., Ltd
4-6-5, Utajima, Nishioyogogawa
Osaka, Japan

Telephone: (06)6477-8425
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I.C Common Name of the Notified Substance

The common name of the notified substance is cyclic dextrin, highly branched.

I.D Conditions of Intended Use in Food

Ezaki intends to market cyclic dextrin, highly branched [trade name Cluster Dextrin® (CCD®)] as a food ingredient in the United States (U.S.) in a variety of traditional food products, including baked goods and baking mixes, beverages and beverage bases, breakfast cereals, tea, grain products, seasonings, milk and plant protein products, processed fruits and vegetables and fruit and vegetable juices, soft candy, and powdered soups. Cyclic dextrin, highly branched will be added to selected ready to eat foods and beverages at maximum use levels of up to 30%. In products requiring further preparation prior to consumption (*i.e.*, beverage powders, powdered seasonings, and dry soup mixes), cyclic dextrin, highly branched will be added at maximum use levels of up to 75%. The resulting cyclic dextrin, highly branched levels will range from 0.25 to 24 g per Reference Amount Customarily Consumed per eating occasion (RACC) (21 CFR 101.12 – U.S. FDA, 2009).

I.E Basis for the GRAS Determination

Pursuant to Title 21, Section 170.30 of the *Code of Federal Regulations* (CFR) (U.S. FDA, 2009), cyclic dextrin, highly branched has been determined to be GRAS on the basis of scientific procedures. This GRAS determination is based on data generally available in the public domain pertaining to the safety of cyclic dextrin, highly branched, as discussed herein, and on consensus among a panel of experts who are qualified by scientific training and experience to evaluate the safety of the cyclic dextrin, highly branched ingredient as a component of food [see Appendix A, entitled "EXPERT PANEL CONSENSUS STATEMENT CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CYCLIC DEXTRIN, HIGHLY BRANCHED FOR USE IN FOODS"].

At the request of Ezaki, an Expert Panel ("the Expert Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, was specially convened on July 15, 2008 to conduct a critical and comprehensive evaluation of the available pertinent data and information, and to determine whether the intended uses of cyclic dextrin, highly branched as a food ingredient are safe and suitable and would be GRAS based on scientific procedures.

The Expert Panel consisted of the following qualified scientific experts: Dr. Joseph F. Borzelleca (Virginia Commonwealth University School of Medicine), Dr. Paul M. Kuznesof (independent consultant), and Dr. William J. Waddell (University of Louisville School of Medicine).

The Expert Panel convened on behalf of Ezaki independently and collectively, and critically evaluated the data and information summarized herein and concluded that the intended uses in

traditional foods described herein for cyclic dextrin, highly branched, meeting appropriate food-grade specifications and manufactured according to current Good Manufacturing Practice (cGMP), are safe and suitable and GRAS based on scientific procedures. It also is the Expert Panel's opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion.

Cyclic dextrin, highly branched is GRAS based on scientific procedures for its intended use as a food ingredient; therefore, it is excluded from the definition of a food additive, and thus, 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.

I.F Availability of Information

The data and information that serve as the basis for this GRAS Notification will be sent to the U.S. Food and Drug Administration (FDA) upon request, or will be available for review and copying at reasonable times at the offices of:

Ezaki Glico Co., Ltd
4-6-5, Utajima, Nishioyogogawa
Osaka, Japan

Should FDA have any questions or additional information requests regarding this notification, Ezaki will supply these data and information.

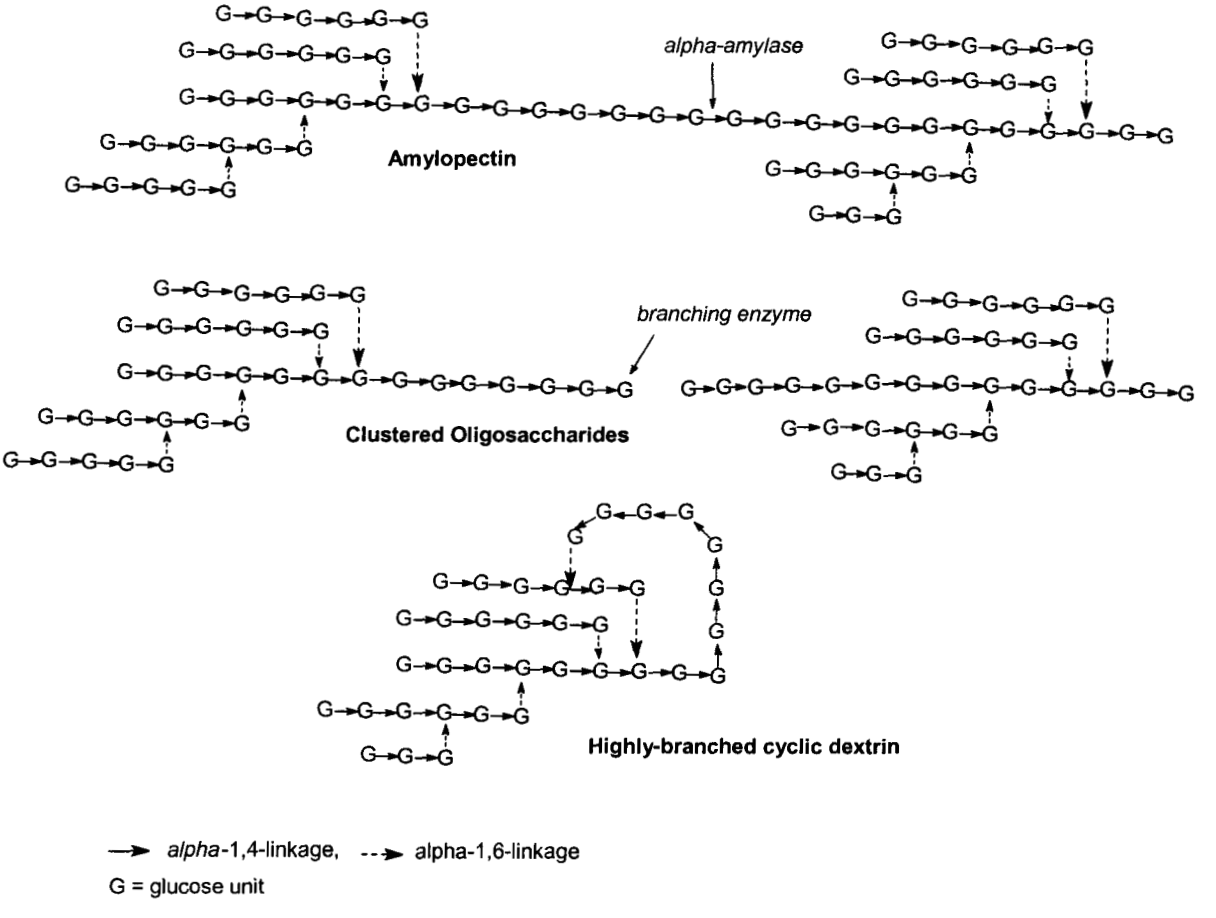
II. Detailed Information About the Identity of the Substance

II.A Identity

The cyclic dextrin, highly branched ingredient is a white odorless powder. The highly-branched cyclic dextrin molecules of the ingredient are branched cyclic oligosaccharides, in which the structural units consist of α-D-glucose monomers. Cyclic dextrin, highly branched comprises of at least 80% highly-branched cyclic dextrin molecules, which are characterized by a molecular weight ranging from 30,000 to 1,000,000 and a weight-average degree of polymerization of 2,500 glucose units. The dextrose equivalent (DE) value of the ingredient, a measure of the reducing power (D-glucose), is <5 (the DE value of dextrose is 100). The short linear chains within the ingredient are composed of α-(1,4)-linked glucose units with branching occurring *via* α-(1,6) glucosidic bonds. The cyclic α-glucan moiety of the cyclic dextrin, highly branched ingredient is linked to the adjacent branched cluster *via* an α-(1,6) glucosidic bond and is composed of 16 to 100 α-linked glucose units. The ingredient also contains small amounts of single glucose molecules (<3.5%) and other saccharide molecules with molecular weights outside the range of the highly-branched cyclic dextrins. The final ingredient is referred to as "cyclic dextrin, highly branched" and a pictorial representation is provided in Figure II.A-1 below.

Common or Usual Name:	Cyclic dextrin, highly branched; highly-branched cyclic dextrin; partially degraded maize starch
Trade Name:	Cluster Dextrin®; CCD®
Chemical Abstracts Service (CAS) Number:	Not applicable
Empirical Formula and Formula Weight:	$(C_6H_{10}O_5)\cdot xH_2O$
Molecular Weight:	30,000 to 1,000,000 g/mol

Figure II.A-1 Pictorial Representation of Various Branched Dextrins, Including a Highly-Branched Cyclic Dextrin



II.B Method of Manufacture

A schematic diagram of the general manufacturing process employed to produce cyclic dextrin, highly branched is illustrated in Figure II.B-1. The starting material for the production of cyclic dextrin, highly branched is derived from waxy corn and consists of unmodified food starch,

which is GRAS based on a history of common use in food. Starch from waxy corn is predominantly in the form of amylopectin, with an amylose content of less than 1% (Buléon *et al.*, 1988). The manufacturing process of cyclic dextrin, highly branched includes 2 sequential enzymatic reactions using safe and suitable enzymes. The first enzymatic reaction involves hydrolysis of the food-grade waxy corn starch with α-amylase (EC 3.2.1.1) derived from non-genetically modified *Bacillus subtilis.* The starch slurry is mixed with the α-amylase solution and rapidly heated. α-Amylase hydrolyzes the α-(1,4) glucosidic bonds between clusters along the main linear chain of amylopectin. Thus, the hydrolysis reaction results in the release of clustered oligosaccharides composed of short linear α-(1,4) glucose chains interlinked *via* α-(1,6) bonds (see Figure II.A-1 in the previous section). As a result of the high temperature heating, the α-amylase is rapidly denatured during the reaction. Following the hydrolysis reaction, the mixture is cooled and the pH adjusted for the second enzymatic step.

The second enzymatic step is mediated by 1,4-α-D-glucan branching enzyme [(1→4)-α-D-glucan:(1→4)-α-D-glucan 6-α-D-[(1→4)-α-D-glucano]-transferase); EC 2.4.1.18; CAS No. 9001-97-2], also known as branching enzyme, derived from a non-genetically modified *Bacillus stearothermophilus* strain TRBE14 or a genetically-modified *B. subtilis* strain 168. The branching enzyme is considered to be safe and suitable for the production of cyclic dextrin, highly branched[1]. It should be noted that the bacteria used to produce the branching enzyme preparation are lysed and removed from the enzyme preparation *via* filtration at the enzyme production stage. Therefore, only a semi-purified filtrate of the enzyme is added to the starting material for the synthesis of cyclic dextrin, highly branched. The branching enzyme is responsible for catalyzing the cyclization reaction within an oligosaccharide cluster *via* intramolecular transglycosylation. The branching enzyme carries out this reaction by transferring a terminal reducing glucose unit from the main α-(1,4) glucose chain to an acceptor glucose unit of the adjacent cluster *via* a α-(1,6) glucosidic bond (see Figure II.A-1 in the previous section). The end product is a highly-branched cyclic dextrin molecule, in which the cyclic α-glucan moiety is reminiscent of cyclodextrin ingredients (*i.e.*, α-, β-, γ-cyclodextrin). During the branching enzyme reaction, sodium hydroxide is added for pH-controlling purposes. Following completion of this second enzyme-catalyzed reaction, the branching enzyme is denatured and inactivated by pH adjustment with hydrochloric acid and high temperature heating. Cyclic dextrin, highly branched is subsequently decolorized by the addition of activated carbon and further purified by filtration through diatomaceous earth, perlite, and an ion-exchange resin. To remove moisture prior to packaging of the final product, the ingredient is subjected to evaporation and spray drying. All processing aids used in the manufacture of cyclic dextrin, highly branched are used in compliance with appropriate federal regulations as indicated in Table II.B-1.

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[1] A GRAS Exemption Claim for 1,4-α-D-glucan branching enzyme derived from non-genetically modified *B. stearothermophilus* strain TRBE14 and genetically-modified *B. subtilis* strain 168 has been concurrently submitted to FDA.

Table II.B-1 List of Enzymes and Processing Aids Used in the Manufacture of Cyclic Dextrin, Highly Branched

Enzyme/Processing Aid	Function	Reference to Appropriate Use in Food
α-Amylase (EC 3.2.1.1) (from non-genetically modified *Bacillus subtilis*)	Hydrolysis of waxy corn starch	No specific regulation pertaining to α-amylase; however, carbohydrase preparations derived from *B. subtilis*, characterized in part by the presence of α-amylase, are affirmed as GRAS for use as direct food substances (21 CFR §184.1148)
1,4-α-D-glucan branching enzyme (EC 2.4.1.18) (from non-genetically modified *Bacillus stearothermophilus* TRBE14 or genetically-modified *B. subtilis* 168)	Catalyzes a cyclization reaction	No specific regulations pertaining to branching enzymes; however, a GRAS Exemption claim for 1,4-α-D-glucan branching enzyme (EC 2.4.1.18) from these same sources has been concurrently submitted to FDA
Ethanol	Preservative for branching enzyme	21 CFR §184.1293 Ethyl alcohol
Diatomaceous Earth	Filter medium	21 CFR §178.3297 Diatomaceous earth
Perlite	Filtration aid	No specific regulations pertaining to perlite; however, perlite is permitted for use as a component of composite filtration media, which are GRAS as filter aids in food processing (GRAS Notice No. GRN 000087)
Activated carbon	Decolorizing agent and filtration aid	No specific regulations pertaining to activated carbon; however, activated carbon is permitted for use as a filtration aid in the treatment of water for the following: 1. the manufacture of distilled alcoholic beverages following treatment with ion-exchange resins (21 CFR §173.25); and 2. the fermentation production of citric acid by *Candida lipolytica* (21 CFR §173.165)
Ion-exchange resins Chloromethylated copolymer of styrene-divinylbenzene and dimethylethanol amine or dimethylamine Sulfonated copolymer of styrene and divinylbenzene	Purification	21 CFR §173.25 Ion-exchange resins
Hydrochloric acid	pH control agent	21 CFR §182.1057 Hydrochloric acid
Sodium hydroxide	pH control agent	21 CFR § 184.1763 Sodium hydroxide

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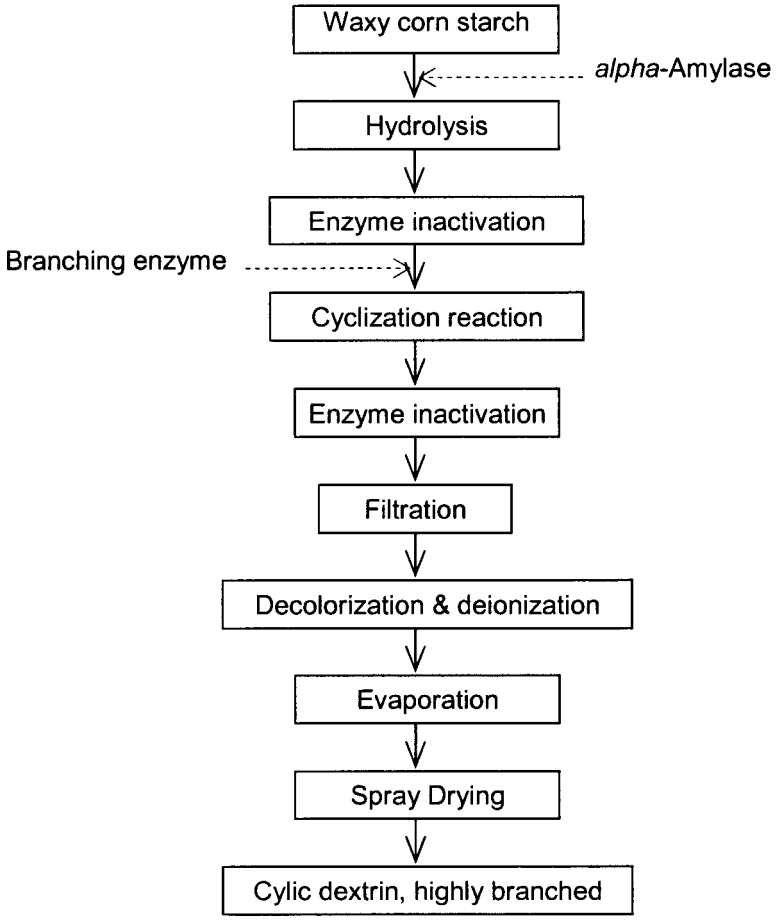
Figure II.B-1 Schematic Overview of the Manufacturing Process for Cyclic Dextrin, Highly Branched



II.C Specifications and Analytical Data for Food Grade Material

Cyclic dextrin, highly branched is produced in accordance with cGMP, and in order to ensure a consistent and safe product, Ezaki has established food-grade specification parameters for the final ingredient. These parameters comprise of specifications for the physical appearance, identification, and purity of cyclic dextrin, highly branched. Not less than 80% of the final product consists of highly-branched cyclic dextrin molecules of molecular weight ranging from 30,000 to 1,000,000. Glucose makes up less than 3.5% of the final product and moisture and ash content account for less than 6% of the final product composition. The remainder of the product (approximately 10%) is composed of saccharide molecules with molecular weights outside the range of the highly-branched cyclic dextrins (*i.e.,* saccharide molecules with molecular weights that are <30,000 or >1,000,000). In addition, several specifications for potential chemical impurities and microbiological contaminants similar to those included for other food ingredients have been included to ensure safety of the use of the ingredient in food. The product specifications for cyclic dextrin, highly branched are the same irrespective of the

source of the branching enzyme that is used to carry out the cyclization reaction. The product specifications for cyclic dextrin, highly branched and the methods of analyses are presented in Table II.C-1 and in Appendix C. Details of the method of analysis for the content of the highly-branched cyclic dextrin molecules are provided in Appendix B.

Analyses of 5 non-consecutive lots (3 for heavy metal analyses) of cyclic dextrin, highly branched confirm that the material produced by the manufacturing process is consistent and complies with the product specifications, meeting appropriate food-grade specifications. The analytical data also demonstrate the absence of any chemical impurities or microbiological contamination. Other analytical data generated by Ezaki confirm the absence of protein and lipid due residual enzyme and bacterial remnants, and of sulfur dioxide used in the production of starch from corn. Details of the methods of analysis for these parameters are provided in Appendix B. The analytical results indicate that protein, lipid, and sulfur were not detected in 3 non-consecutive lots of cyclic dextrin, highly branched, thus demonstrating successful removal of the production enzymes and bacterial remnants during the filtration process and the absence of sulfur in the final ingredient. A summary of the analytical data and complete certificates of analysis for these lots are provided in Appendix C.

Table II.C-1 Product Specifications for Cyclic Dextrin, Highly Branched

Specification Parameter	Specification Requirement	Method of Analysis
Appearance	White powder	Visual examination
Odor	Odorless	Sensory analysis
Foreign matter	Negative	Visual examination
Dextrose equivalents	Less than 5	Modified Somogyi-Nelson method[a,b]
Assay (HBCD content) (%)	Not less than 80	HPLC analysis[c]
Glucose (%)	Less than 3.5	FCC[d] HPLC analysis
Saccharides <30,000 MW (excluding glucose) and >1,000,000 MW (%)	Less than 14	Calculated by difference[e]
Loss on drying (%)	Less than 5.5	FCC Loss on drying
Residue on ignition (%)	Less than 0.05	FCC Residue on ignition
Heavy metals		
Heavy metals (ppm)	Less than 4	FCC Colorimetric analysis
Arsenic (As_2O_3) (ppm)	Less than 1	FCC AAS
Lead (ppm)	Less than 1	FCC AAS
Microbiological Parameters		
Standard plate count (CFU/g)	Less than 300	BAM[f], Chapter 3, Conventional Plate Count Method
Coliform count	Negative	BAM, Chapter 4, Conventional Method for Determining Coliforms and *Escherichia coli*

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Table II.C-1 Product Specifications for Cyclic Dextrin, Highly Branched

Specification Parameter	Specification Requirement	Method of Analysis
Yeasts (CFU/g)	Less than 50	BAM, Chapter 18, Enumeration of Yeast and Mold in Food – Dilution Plating Technique
Molds (CFU/g)	Less than 50	BAM, Chapter 18, Enumeration of Yeast and Mold in Food – Dilution Plating Technique

As_2O_3 = Arsenic oxide; AAS = Atomic Absorption Spectrometry; BAM = Bacteriological Analytical Manual Online; CFU = Colony-forming units; FCC = Food Chemicals Codex; HBCD = Highly-branched cyclic dextrin; HPLC = High-performance liquid chromatography.
[a] Nelson, N.J. 1944. A photometric adaptation of the Somogyi method for the determination of glucose. J. Biol. Chem. 153, 375.
[b] Somogyi, M. 1952. Notes on sugar determination. J. Biol. Chem. 195, 19.23.
[c] See Appendix B for details on the method of analysis.
[d] FCC. 2008. Food Chemicals Codex, 6th ed. United States Pharmacopeial Convention (USP). Rockville, Maryland.
[e] On dry basis, total carbohydrate content – HBCD content – glucose content.
[f] U.S. FDA. 2001. Bacteriological Analytical Manual [BAM] Online. U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN); College Park, Maryland. Available from: http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm.

II.D Additional Chemical Analyses

II.D.1 Pesticide/Herbicide Analysis

For a typical lot of corn imported from the U.S. to Japan, pesticide screening, comprising over 400 substances, is conducted on an annual basis. The substance list is based on the list published by the Japanese Ministry of Health, Labour, and Welfare and includes pesticides for which FDA has established action levels. Results of analysis indicate that the levels of these substances in corn are below the limits of detection and comply with the action levels established by FDA for poisonous or deleterious substances in human food (U.S. FDA, 2000a) as summarized in Table II.D.1-1. Additionally, the Japanese Starch & Sweeteners Industry Association lists 69 substances as major chemicals used in the U.S. and also requires that testing is conducted for levels of these substances once a year. The list provided by the Japanese Starch & Sweeteners Industry Association is based on the U.S. usage status of chemicals appearing in the U.S. Department of Agriculture (USDA) Agricultural Chemical Usage Field Crops Summaries for the years 2000 through 2008. Again, analytical results indicate that the levels of these substances in corn are below the limits of detection. The association additionally lists 8 major pesticides/herbicides that should be monitored on a regular basis, and which include aluminum phosphide, malathion, pirimiphos-methyl, atrazine, acetochlor, fenitrothion, glufosinate, and glyphosate. Ezaki monitors the levels of these 8 chemicals for every lot of corn and the analytical results confirm the absence of these pesticide residues in the corn starting material. A summary of the analytical data and complete certificates of analysis are provided in Appendix C.

Table II.D.1-1 Summary of the Food and Drug Administration (FDA)'s Action Levels for Pesticides Cereal Grains

Substance	Commodity	Action Level (ppm)
Aldrin/Dieldrin	Cereal grains	0.02
Benzene hexachloride (BHC)	Cereal grains	0.05
Chlordane	Corn	0.1
Dichloro-diphenyl-trichloroethane (DDT)	Cereal grains	0.5
	Corn, fresh sweet	0.1
Heptachlor/Heptachlor epoxide	Cereal grains	0.01
Lindane	Corn, fresh sweet	0.5
	Corn	0.1

II.D.2 Mycotoxin Analysis

Since mycotoxins are known contaminants of corn, the waxy corn starch used in the manufacture of cyclic dextrin, highly branched also was analyzed for mycotoxin content (aflatoxin and fumonisin). FDA has established an action level of 20 ppm for aflatoxin in food (U.S. FDA, 2000a). The analytical results showed no detectable levels of aflatoxin B_1 and B_2 or fumonisin B_1 and B_2 in the waxy corn starch at a limit of detection of 1 ppb for aflatoxin and 0.05 ppm for fumonisin. A summary of the analytical data and certificates of analysis are provided in Appendix C.

II.D.3 Residual Solvent Analysis

Small quantities of ethanol are added to the branching enzyme preparations used in the production of the cyclic dextrin, highly branched ingredient. As a result of its addition to the branching enzyme preparation, ethanol is present in the reaction mixture at the cyclization step at a level of 0.15 to 0.25 % (w/w) (or 1,500 to 2,500 ppm), which is consistent with its use as a permitted solvent at a residual level of 3.5% by weight for the extraction of fish protein isolates (21 CFR §172.340). Furthermore, since several steps in the production of the ingredient involve high temperature heating (*i.e.*, during the inactivation of the enzymes and evaporation and spray drying steps), the added ethanol is expected to evaporate, and thus, be removed during processing. In addition, considering the amount of naturally occurring ethanol in different food products, the amount of any residual ethanol in cyclic dextrin, highly branched will be minimal and will have no significant impact on human health, particularly with respect to current ethanol exposures.

II.D.4 Phytate Analysis

Phytic acid (phytate) is present in the hulls of grains, including maize, and is a known chelator of minerals. Although an analysis for phytic acid levels of manufactured lots of cyclic dextrin, highly branched was not conducted, the hulls of the waxy corn utilized in the manufacture of

cyclic dextrin, highly branched are removed prior to processing, thus minimizing the possibility for the presence of phytic acid in the final product. In addition, the application of ion-exchange resins during the manufacturing process would remove residual amounts of phytic acid along with other ionic substances.

II.E Viscosity Analysis

Viscosity of a single lot of manufactured CCD was measured at 23°C with the use of a rotational viscometer at a shear rate of 200 L/s. Maximal viscosity of 19,000 mPa·s was achieved at a concentration of approximately 50%. The viscosity of CCD is slightly greater than that of a conventional dextrin with a DE value of 2 to 5 and significantly greater than that of a conventional dextrin with a DE value of 8 to 10. The analytical data are provided in Appendix D.

II.F Stability of Cyclic Dextrin, Highly Branched

The stability of the cyclic dextrin, highly branched ingredient is characterized by the stability of the highly-branched cyclic dextrin molecule content. Stability of CCD was evaluated following long-term storage periods of 25 to 77 months. The stability of samples from 4 lots of the ingredient was evaluated following long-term storage periods of 25 to 77 months at room temperature. Specifically, the sample lots were stored at room temperature for up to 77 months and were analyzed for highly-branched cyclic dextrin content by high-performance liquid chromatography (HPLC) at 0 (study initiation) and at 25, 36, 47, or 77 months. The highly-branched cyclic dextrin content of the bulk ingredient remained stable for the duration of the storage period (up to 77 months) as shown in Table D-1. The analytical data are provided in Appendix D.

III. Self-Limiting Levels of Use

Cyclic dextrin, highly branched is viscous and does not readily dissolve in solution at high concentrations (approximately ≥50% w/v). Therefore, the use of cyclic dextrin, highly branched in solution-based products at high concentrations is self-limiting based on its viscosity and solubility properties. For practical purposes, the use level of cyclic dextrin, highly branched is limited to 30% w/v.

IV. Basis for GRAS Determination

IV.A Documentation to Support the Safety of Cyclic Dextrin, Highly Branched

The determination that cyclic dextrin, highly branched is GRAS is on the basis of scientific procedures, and the information supporting the general recognition of the safe use of this ingredient includes:

- data pertaining to the identity, intended use, and estimated intake of cyclic dextrin, highly branched;
- the metabolic fate of cyclic dextrin, highly branched; and
- preclinical and human studies conducted with cyclic dextrin, highly branched and the largest naturally-produced cyclodextrin permitted in food (γ-cyclodextrin) in the U.S.

Moreover, these data were reviewed by a panel of experts, qualified by scientific training and experience to evaluate the safety of ingredients as components of food, who concluded that the intended uses of cyclic dextrin, highly branched are safe and suitable and would be GRAS based on scientific procedures [see Appendix A, entitled, "EXPERT PANEL CONSENSUS STATEMENT CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CYCLIC DEXTRIN, HIGHLY BRANCHED FOR USE IN FOODS"]. A summary of these data is presented herein.

IV.B Intended Use of Cyclic Dextrin, Highly Branched in Food

IV.B.1 Natural Occurrence and Dietary Consumption of Cyclic α-Glucans

While highly-branched cyclic dextrins are not prevalent or widely identified in conventional foods, the concomitant presence of starches with α-amylases and transferases in many foods has been reported to result in the formation of small amounts of cyclic α-glucans (Nishimura *et al.*, 1996). Therefore, background dietary exposure to branched cyclic α-glucans from their natural occurrence in foods could be assumed, although it is likely minimal. In Japan, cyclic dextrin, highly branched has been permitted for use in food since 2002, and therefore, the ingredient has a recently established dietary intake from its addition to foods of the Japanese diet. Uses of cyclic dextrin, highly branched in food in Japan include components of sports drinks, as a flavoring agent, and as a spray drying aid.

As mentioned, the cyclic α-glucan moiety of the highly-branched cyclic dextrin molecules is reminiscent of cyclodextrins [cyclic oligosaccharides, consisting of α-(1-4)-linked α-D-glucose units (*i.e.*, cyclic α-(1-4) glucans)], which also are formed naturally from the action of glucanotransferases on starch components (Li *et al.*, 2007). The predominant cyclodextrins formed are α-, β-, and γ-cyclodextrin, along with trace amounts of larger ring cyclodextrins. Cyclodextrins are GRAS for use in selected foods (GRN Nos. 000155, 000074, and 000046 for cyclodextrin, respectively) (U.S. FDA, 2000b, 2001, 2004) and have an established recent

history of human consumption as a result of their recent application in the food industry (Cravotto *et al.*, 2006).

IV.B.2 Estimated Intake of Cyclic Dextrin, Highly Branched

Estimates for the intake of cyclic dextrin, highly branched were based on the intended food uses and use levels in conjunction with food consumption data included in the National Center for Health Statistics' (NCHS) 2003-2004 National Health and Nutrition Examination Survey (NHANES) (CDC, 2006; USDA, 2009). The individual intended food uses and use levels of cyclic dextrin, highly branched are presented in Table IV.B.2-1. Of note, the intended food uses of cyclic dextrin, highly branched do not include meat and poultry or meat and poultry-containing products, including soups and soup mixes. Food codes representative of each intended food use were chosen from the 2003-2004 NHANES (CDC, 2006; USDA, 2009) and were grouped in food use categories according to Title 21, Section 170.3 of the CFR (U.S. FDA, 2009). Product-specific adjustment factors were developed based on data provided in the standard recipe file for the Continuing Survey of Food Intakes by Individuals (CSFII) 1994-1996, 1998 survey (USDA, 2000).

Table IV.B.2-1 Summary of the Individual Proposed Food Uses and Use Levels for Cyclic Dextrin, Highly Branched in the U.S.

Food Category	Proposed Food Uses	Maximum Use-Level (%)	RACC[a]	Maximum Use-Level (g/RACC)
Baked Goods and Baking Mixes	Cookies	10	30 g	3
Beverages and Beverage Bases	Energy, Sport, and Isotonic Drinks	10 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	24 (RTD) 11 (Powder)
	Enhanced and Bottled Waters	3	240 mL	24
	Fruit Flavored Drinks	3 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	7 (RTD) 11 (Powder)
	Non-Milk Based Meal Replacement Beverages	10 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	24 (RTD) 11 (Powder)
Breakfast Cereals	Ready to Eat Breakfast Cereals	10	15 to 55 g	1.5 to 5.5
Coffee and Tea	Tea, Including Flavored Tea	3 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	7 (RTD) 11 (Powder)
Grain Products and Pastas	Cereal, Energy, and Nutrition Bars	30	55 g	17
Herbs, Spices, Seasonings, and Flavorings	Powdered Seasonings	50	0.5 g	0.25
Milk Products	Flavored Milk and Milk Drinks	10 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	24 (RTD) 11 (Powder)
	Milk-Based Meal Replacement Beverages	10 (RTD) 75 (Powder)	240 mL (RTD) 15 g (Powder)	24 (RTD) 11 (Powder)
Plant Protein Products	Soy Based Bars	30	55 g	17
	Soy Milk	10	240 mL	24

Table IV.B.2-1 Summary of the Individual Proposed Food Uses and Use Levels for Cyclic Dextrin, Highly Branched in the U.S.

Food Category	Proposed Food Uses	Maximum Use-Level (%)	RACC[a]	Maximum Use-Level (g/RACC)
Processed Fruits and Fruit Juices	Fruit Juices	3	240 mL	3
	Nectars	3	240 mL	3
Processed Vegetables and Vegetable Juices	Vegetable Juices	3	240 mL	3
Soft Candy	Chocolate Confectionary	10	40 g	4
Soups and Soup Mixes	Dry Soup Mixes	50	15 g	8

RACC = Reference Amount Customarily Consumed Per Eating Occasion (21 CFR 101.12 – U.S. FDA, 2010 - http://edocket.access.gpo.gov/cfr_2009/aprqtr/pdf/21cfr101.12.pdf); RTD = Ready-to-Drink

[a] U.S. FDA. 2009. Part 101—Food labeling. § 101.12— Reference amounts customarily consumed per eating occasion. In: U.S. Code of Federal Regulations (CFR). Title 21—Food and Drugs (Food and Drug Administration). U.S. Government Printing Office (GPO); Washington, DC, pp. 46-56.

The estimated intakes of cyclic dextrin, highly branched from all intended food uses in the U.S. are presented in Tables IV.B.2-2 and IV.B.2-3 on an absolute and body weight basis, respectively. From the intakes analysis, approximately 91.3% of the total U.S. population was identified as potential consumers of the ingredient from the intended food uses (7,547 actual users identified). Of all the population groups, children were determined to be the greatest percentage of users at 99.4%, followed by female and male teenagers at 95.4 and 93.9%, respectively. Infants were determined to be the lowest percentage of users at 73.0%.

Table IV.B.2-2 Summary of the Estimated Daily Intake of Cyclic Dextrin, Highly Branched from All Proposed Food Uses in the U.S. by Population Group (2003-2004 NHANES Data)

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-Users Consumption	
				Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Infant	0-2	73.0	679	13	33	16	38
Child	3-11	99.4	1,279	25	50	25	50
Female Teenager	12-19	95.4	946	17	40	19	41
Male Teenager	12-19	93.9	938	27	57	28	58
Female Adult	20 and Up	92.7	1,973	18	39	19	41
Male Adult	20 and Up	89.8	1,732	21	52	24	57
Total Population	All Ages	91.3	7,547	20	46	22	48

000019

Table IV.B.2-3 Summary of the Estimated Daily Per Kilogram Body Weight Intake of Cyclic Dextrin, Highly Branched from All Proposed Food Uses in the U.S. by Population Group (2003-2004 NHANES Data)

Population Group	Age Group (Years)	% Users	Actual # of Total Users	All-Person Consumption		All-Users Consumption	
				Mean (mg/kg)	90th Percentile (mg/kg)	Mean (mg/kg)	90th Percentile (mg/kg)
Infant	0-2	73.0	679	1,068	2,816	1,310	3,062
Child	3-11	99.4	1,279	963	1,990	973	1,990
Female Teenager	12-19	95.4	946	306	704	328	710
Male Teenager	12-19	93.9	938	433	917	456	923
Female Adult	20 and Up	92.7	1,973	254	583	274	600
Male Adult	20 and Up	89.8	1,732	251	592	282	655
Total Population	All Ages	91.3	7,547	391	939	425	1,011

For the total U.S. population, consumption of foods containing cyclic dextrin, highly branched would result in estimated mean all-person and all-user intakes of the ingredient of 20 g/person/day (391 mg/kg body weight/day) and 22 g/person/day (425 mg/kg body weight/day), respectively (Tables IV.B.2-2 and IV.B.2-3). The 90th percentile all-person and all-user intakes of the ingredient by the total population from all intended food uses were estimated to be 46 g/person/day (939 mg/kg body weight/day) and 48 g/person/day (1,011 mg/kg body weight/day), respectively.

On an individual population basis, the greatest mean all-person and all-user intakes of cyclic dextrin, highly branched on an absolute basis were determined to be in male teenagers at 27 and 28 g/person/day, respectively (Table IV.B.2-2). Infants were determined to have the lowest mean all-person and all-user intakes of cyclic dextrin, highly branched on an absolute basis, with values of 13 and 16 g/person/day, respectively. On a per kilogram body weight basis, mean all-person and all-user intakes of cyclic dextrin, highly branched were highest in infants, with intakes of 1,068 and 1,310 mg/kg body weight/day, respectively (Table IV.B.2-3). The lowest all-person mean intakes on a per kilogram body weight basis were determined to be in male adults, with a value of 251 mg/kg body weight/day, while the lowest mean all-user intake was determined to be in female adults with a value of 274 mg/kg body weight.

When heavy consumers (90th percentile) were assessed on an absolute basis, all-person and all-user intakes of cyclic dextrin, highly branched from all intended food uses also were determined to be greatest in male teenagers, with values of 57 and 58 g/person/day, respectively. The lowest 90th percentile intakes again were in infants, with all-person and all-user intakes of 33 and 38 g/person/day, respectively, on an absolute basis. On a per kilogram body weight basis, infants were determined to have the greatest all-person 90th percentile intake of the ingredient with a value of 2,816 mg/kg body weight/day, as well as the highest all-user 90th percentile intake of the ingredient with a value of 3,062 mg/kg body weight/day. The lowest

all-person and all-user 90th percentile intakes of cyclic dextrin, highly branched on a body weight basis were determined to be in female adults at 583 and 600 mg/kg body weight/day, respectively.

Although the highest 90th percentile all-user intake of cyclic dextrin, highly branched on a body weight basis was determined to be in infants (3,062 mg/kg body weight/day), this value may not represent the most realistic intake assessment of the ingredient in infants. While cyclic dextrin, highly branched is intended for use in foods that may be consumed by infants, it is not intended for use in infant-specific foods, such as infant formulas and baby foods, and none of the specified food uses are intended to be marketed to infants. As a result, the intake of foods containing cyclic dextrin, highly branched by infants are likely to be limited, and the 90th percentile all user intake of the ingredient by children (1,990 mg/kg body weight/day) may represent a more appropriate estimate for the highest 90th percentile all-user intake on a body weight basis.

Furthermore, the type of methodology employed in the intake assessment is generally considered to be 'worst case' as a result of several conservative assumptions made in the consumption estimates. For example, it is often assumed that all food products within a food category contain the ingredient at the maximum specified level of use. In addition, it is well established that the length of a dietary survey affects the estimated consumption of individual users; short-term surveys, such as the typical 2- or 3-day dietary surveys, overestimate the consumption of food products that are consumed relatively infrequently. Therefore, the calculated estimated intake levels of the cyclic dextrin, highly branched ingredient are highly conservative estimates.

IV.C Metabolic Fate of Cyclic Dextrin, Highly Branched

IV.C.1 Overview of Normal Dietary α-Glucan Digestion

Cyclic dextrin, highly branched consists of modified food starch, and therefore, is subjected to normal dietary α-glucan digestion. This historically well-known process involves sequential and efficient digestion of the dietary α-glucan, such as starch (amylose and amylopectin), to glucose within the gastrointestinal (GI) tract. Digestion is initiated by salivary α-amylase in the mouth and continues in the intestine with the release of pancreatic α-amylase. α-Amylase catalyzes a hydrolysis reaction, resulting in the cleavage of α-(1,4) glucosidic bonds occurring between glucose units. The hydrolysis reaction catalyzed by α-amylase results in the release of the disaccharide maltose [2 α-(1,4)-linked glucose units], as well as the trisaccharide maltotriose. α-Amylase does not further catabolize maltose or maltotriose as the specificity of α-amylase is for larger oligosaccharides. Thus, α-amylase-mediated hydrolysis does not result in the production of glucose monomers within the intestinal lumen. In addition, due to steric hindrance, α-amylase is unable to cleave α-(1,4) bonds at branching points. As a result, α-limit dextrins, a chain of α-(1,4)-linked glucose units that begins with an α-(1,6) bond, are formed in

addition to maltose and maltotriose. Further digestion of these oligosaccharides (maltose, maltotriose, and α-limit dextrin) is accomplished by the "maltases", glucoamylase and sucrase-α-dextrinase (also referred to as sucrase-isomaltase) (Würsch, 1991; Gray, 1992). Glucoamylase sequentially releases single units of glucose from the non-reducing end of an oligosaccharide by catalyzing the hydrolysis of α-(1,4) bonds. The sucrase subunit of sucrase-α-dextrinase also cleaves α-(1,4) bonds with a substrate preference for shorter oligosaccharides, such as maltose and maltotriose. Finally, the α-dextrinase subunit specifically cleaves the α-(1,6) bond of terminal α-(1,6)-linked glucose units, the products of which are subject to further glucoamylase or sucrase activity. Each enzyme releases one glucose unit at a time, and thus, the final product of starch digestion is glucose, the only absorbable product of dietary α-glucan digestion (*i.e.*, there is no mechanism in place for the absorption of oligo- or polysaccharides).

Dietary cyclic α-glucans, such as cyclodextrins (*i.e.*, α-, β-, and γ-cyclodextrin) and branched cyclodextrins (*e.g.*, maltosyl-β-cyclodextrin), undergo a similar digestive process as starch components, with ring-opening occurring as the first step. The digestion of cyclodextrins is mediated by α-amylase, which cleaves an α-(1,4) bond, resulting in ring opening and formation of a linear oligosaccharide (Abdullah *et al.*, 1966; Kondo *et al.*, 1990). In cases of branched cyclodextrins, hydrolysis (cleavage) of the branches may occur prior to ring opening (Hirayama *et al.*, 1992). Subsequently, beginning at the reducing end, α-amylase hydrolyzes the linearized oligosaccharides into maltotriose and maltose, in addition to small amounts of glucose (Abdullah *et al.*, 1966; Marshall and Miwa, 1981; Kondo *et al.*, 1990). Further digestion within the GI tract results in the efficient digestion of cyclodextrin structures consisting of at least 8 glucose units to glucose (De Bie *et al.,* 1998; Asp *et al.*, 2006). The rate of hydrolysis of cyclodextrins increases with increasing ring size (Marshall and Miwa, 1981; Kondo *et al.*, 1990) as a result of the greater flexibility and conformational freedom associated with larger ring oligosaccharides (Ivanov and Jaime, 2004; Gotsev *et al.*, 2007; Maestre *et al.*, 2007), allowing for easier binding of the substrate to the enzyme (*i.e.,* no steric hindrance).

Glucose, the final product of dietary α-glucan digestion, is transported from the intestinal lumen into enterocytes *via* secondary active transport carried out by the sodium-coupled glucose cotransporter (SGLT1) (Drozdowski and Thomson, 2006). Transport of glucose across the basolateral membrane of enterocytes into the circulation occurs by facilitated transport carried out by glucose transporter 2 (GLUT2). Once systemically absorbed, glucose is utilized in well-characterized metabolic pathways as a source of energy. Although the digestion of starch components and other dietary α-glucans is extremely efficient, some polysaccharide molecules and cyclic oligosaccharides, may pass through the small intestine as a result of incomplete digestion and become subject to microbial fermentation in the large intestine (Stephen, 1991; Würsch, 1991; Brown, 1996; De Bie *et al.,* 1998; Topping and Clifton, 2001). Short-chain fatty acids are produced from the fermentation process, which are absorbed from the lower intestine and further metabolized to produce energy.

IV.C.2 Studies Conducted to Characterize the Metabolic Fate of Cyclic Dextrin, Highly Branched

The tests performed to confirm the metabolic fate of the highly-branched cyclic dextrin molecules included *in vitro* hydrolysis testing in the presence of human salivary or porcine pancreatic α-amylase or rat intestinal homogenate. The results of specific testing on cyclic dextrin, highly branched confirm that the ingredient undergoes normal dietary α-glucan digestion to glucose, as described in Section IV.C.1. Such results were as expected, considering that the highly-branched cyclic dextrin molecules are products of starch (amylopectin) hydrolysis/ modification and that the large-ring cyclic α-glucan structure possesses high flexibility and conformational freedom, allowing easy access to digestive enzymes. In addition, indirect evidence of complete hydrolysis of the highly-branched cyclic dextrin molecules was obtained from animal and human studies evaluating blood glucose levels following consumption of the ingredient as described below.

IV.C.2.1 *In Vitro* Studies

In order to ascertain the extent and time-course of hydrolysis of the highly-branched cyclic dextrin molecules by human α-amylases, the ingredient was incubated with human salivary α-amylase for 0, 20, 60, 360, or 1,440 minutes (Choi *et al.*, 2009). Enzyme activity was terminated by heating samples at 100°C. For comparison, conventional dextrins with DE values of 3 and 16 (DE3 and DE16, respectively) also were incubated with human salivary α-amylase. Within 20 minutes of incubation, hydrolysis of the highly-branched cyclic dextrin molecules resulted in the formation of glucose, maltose, maltotriose, and other small oligosaccharides as determined by thin layer chromatography (TLC). The abundance of these reaction products was shown to increase with the duration of the incubation period. Maltose and maltotriose were the principal hydrolysis products formed, followed by smaller amounts of glucose. Incubation of DE3 and DE16 with human salivary α-amylase produced a similar pattern of digestion following a similar time-course. When cyclic dextrin, highly branched, DE3, and DE16 were incubated with porcine pancreatic α-amylase, the oligosaccharide reaction products were again predominantly maltose and maltotriose with formation occurring within 20 to 60 minutes. Complete hydrolysis of the highly-branched cyclic dextrin molecules, however, was not observed with the α-amylases. In contrast, incubation of cyclic dextrin, highly branched with rat intestinal homogenate resulted in complete digestion to glucose. Maltose, maltotriose, and glucose were initially formed within 20 minutes, with levels of maltose and maltotriose substantially reduced at 360 minutes with a concomitant increase in glucose levels. Similar results were observed with DE3 and DE16. The formation of glucose continued to increase up to at least 1,440 minutes, while levels of maltose and maltotriose continued to decline. Measurement of the amount of glucose produced, determined using the glucose oxidase method, demonstrated that the rate of digestion to glucose was most rapid within the first 120 minutes. Thirty three percent (33%) of cyclic dextrin, highly branched was digested to glucose by 120 minutes, 70% by 360 minutes, and 100% by 1,440 minutes, indicating that the ingredient

is completely hydrolyzed to glucose by intestinal enzymes. The results obtained with DE3 and DE16 were comparable to those for cyclic dextrin, highly branched. The results of this set of experiments indicate that the digestion profile of cyclic dextrin, highly branched is very similar to conventional dextrins. Specifically, the cyclic dextrin, highly branched ingredient is digested by human salivary α-amylase to small oligosaccharides and is completely digested to glucose *via* the action of intestinal digestive enzymes.

IV.C.2.2 Animal Studies

Indirect evidence for the digestibility of cyclic dextrin, highly branched *in vivo* was demonstrated in a study conducted with male Std ddY mice administered a single dose of a 5% cyclic dextrin, highly branched solution (300 µL) by oral gavage following fasting (Takii *et al.*, 1999). Control animals were given either water or a 5% glucose solution. Blood samples were collected at 0, 5, 10, 20, and 30 minutes after dosing for analysis of blood glucose and insulin concentrations. Blood glucose levels increased within 5 minutes of cyclic dextrin, highly branched administration, with peak concentrations of approximately 80 mg/dL occurring at 10 minutes. The increase in blood glucose was sustained for up to 20 minutes and was observed to decline at 30 minutes. A similar pattern was observed in mice administered glucose, except that peak blood glucose concentrations (approximately 125 mg/dL at 10 minutes) were significantly higher compared to those following administration of cyclic dextrin, highly branched. Increases in blood insulin concentrations were noted 10 minutes post-dosing and were sustained for up to at least 30 minutes in both the cyclic dextrin, highly branched and glucose groups. No significant differences in blood insulin levels were observed between glucose- and cyclic dextrin, highly branched-administered mice. In a subsequent experiment, mice were administered 500 mg/kg body weight of cyclic dextrin, highly branched or glucose following 10 minutes of swimming (exercise). Blood glucose and insulin levels were significantly increased in both the cyclic dextrin, highly branched- and glucose-administered mice compared to the water controls as assessed 10 minutes following administration (20 minutes following the beginning of the swimming exercise). Blood glucose and insulin levels, however, were significantly elevated in glucose-administered mice compared to those administered cyclic dextrin, highly branched.

The results from this study demonstrate that oral administration of cyclic dextrin, highly branched results in a rise in blood glucose levels and in an insulin response, suggesting that the ingredient is digested to glucose in the GI tract of the whole animal. Of note, however, cyclic dextrin, highly branched produced lower glycemic and insulin responses than glucose. This observation is most likely attributable to the time afforded to the digestion of cyclic dextrin, highly branched to glucose, resulting in a more gradual absorption of glucose. In contrast, glucose does not require further enzymatic digestion prior to absorption, and therefore, is more readily absorbed from the GI tract.

IV.C.2.3 Human Studies

Takii *et al.* (2004) investigated the differences in postprandial blood glucose levels in human volunteers following consumption of DE16- and cyclic dextrin, highly branched-based sports drinks during exercise. The study was conducted in 7 untrained men who were provided with prototype sports drinks containing either cyclic dextrin, highly branched, a commercial dextrin (DE16), or glucose. Each carbohydrate-based drink was composed of 10% carbohydrate, providing approximately 35 g of carbohydrate per person. Water was used as a control. The subjects consumed the drinks immediately after completing 3 minutes of cycling, following which, they were permitted a 10-minute rest. The subjects then completed a further 30 minutes of cycling. Postprandial blood glucose was measured in subjects at 10 minute intervals starting from immediately prior to consumption of the test drinks. Compared to baseline measurements, postprandial blood glucose levels were significantly increased upon consumption of the carbohydrate-based drinks, but significantly reduced upon consumption of water alone. The increases in blood glucose levels observed were similar following consumption of the glucose-, DE16-, and cyclic dextrin, highly branched-based sports drinks. Peak blood glucose concentrations occurred at 20 minutes following consumption of the test drinks and were similar following intake of cyclic dextrin, highly branched- and glucose-containing drinks (approximately 25 mg/dL). The significant rise in blood glucose levels following consumption of the cyclic dextrin, highly branched-based drink is indicative of glucose absorption, demonstrating that the cyclic dextrin, highly branched ingredient is digested to glucose in humans.

Thus, the available evidence demonstrates that cyclic dextrin, highly branched is efficiently digested to glucose, a safe product of carbohydrate digestion. Larger cyclic dextrin, highly branched molecules with higher degrees of polymerization may escape complete hydrolysis as a result of their size. Consequently, these larger molecules may be incompletely digested in the small intestine and will pass into the lower GI tract where they will be subjected to microbial fermentation in keeping with the well-known process of dietary α-glucan digestion as described in Section IV.C.1 (Stephen, 1991; Würsch, 1991; Brown, 1996; De Bie *et al.,* 1998; Topping and Clifton, 2001).

IV.D Toxicological Studies

The cyclic dextrin, highly branched ingredient does not pose any safety concerns given that modified food starches are prevalent constituents of the human diet with a long history of safe use in food and that the ingredient is efficiently digested to glucose, which is a safe product of carbohydrate digestion. The results of ingredient-specific toxicity tests support the safety of cyclic dextrin, highly branched. Such tests included an acute oral toxicity test and an *in vitro* mutagenicity test and are summarized in Section IV.D.1 and Section IV.D.4, respectively.

The safety of the ingredient is further discussed in terms of the large cyclic α-glucan moiety occurring within the highly-branched cyclic dextrin molecules. The discussion arises

considering that the cyclic moiety may be cleaved from the branched clusters during digestion and that such cyclic α-glucans do not have an established history of safe use in food in the U.S. The safety of the cyclic moiety is discussed using supportive data on γ-cyclodextrin, which is the largest cyclodextrin currently permitted for use in food in the U.S. Although cyclic dextrin, highly branched and γ-cyclodextrin are not structurally identical, their cyclic structures, although also not identical, share similarities in that both are cyclic α-glucans with a common metabolic fate consisting of efficient digestion to glucose within the GI tract. Thus, toxicological studies on γ-cyclodextrin were considered to be appropriate for further discussing the safety of the cyclic α-glucan moiety of the highly branched cyclic dextrin molecules. These studies are summarized below in Section IV.D.1 through to Section IV.D.4. The branched clusters of the highly-branched cyclic dextrin molecules are derived from amylopectin, and thus, are not further discussed considering that starch components possess a long history of safe consumption in humans.

IV.D.1 Acute Toxicity Studies

Cyclic dextrin, highly branched was assessed for acute oral toxicity in a study performed according to the Japanese Ministry of Health and Welfare (MHW) Ordinance No. 21 (Choi *et al.*, 2009). In this study, 5 male and 5 female SLC-Wistar rats were weighed and then administered a single dose of 2,000 mg/kg body weight of cyclic dextrin, highly branched by oral gavage following a 16-hour fast. The animals were fasted for a further 3 hours following administration. For the 6 hours immediately following administration of the test substance, the rats were observed at 1-hour intervals and then every day thereafter for a period of 14 days. On weekdays, the animals were observed twice daily and on weekend days, they were observed once daily. Viability, as well as signs of toxicity, were assessed and documented. Body weights were recorded on Days 7 and 14 of the observation period. All animals were killed on Day 14 of the observation period and organs examined upon necropsy. None of the animals died during the 14-day observation period. At 5 and 6 hours post-administration, all animals displayed loose stools, the effect of which had resolved upon re-examination at 24 hours. Loose stools were considered not toxicologically significant as this is a physiological effect that is well-known to be caused by the incomplete digestion of large bolus doses of carbohydrates (Bär, 1985; Newberne *et al.*, 1988). Such an effect, however, is not expected in humans at the estimated daily intakes based on the results of a human study (Takii *et al.*, 2004; discussed in Section IV.E.1), and considering that the daily intakes of cyclic dextrin, highly branched are resultant of smaller intakes throughout the day and not due to large bolus intakes. No further abnormalities were observed in the general condition of the animals at any time point, and all rats displayed satisfactory body weight changes throughout the observation period. Furthermore, no compound-related macroscopic abnormalities were detected upon necropsy in any of the animals. Based on the absence of mortality following oral administration of 2,000 mg/kg body weight of cyclic dextrin, highly branched, the investigators determined that the oral LD_{50} of cyclic dextrin, highly branched is greater than 2,000 mg/kg body weight. Therefore, based on the

results of this study, cyclic dextrin, highly branched is not acutely toxic following oral exposure in rats.

In support of the low toxicity of large-ring cyclic α-glucans, γ-cyclodextrin has been shown to have low acute oral toxicity in rats and mice (*i.e.,* LD_{50} values of >8 and >15 g/kg body weight, respectively) (Matsuda *et al.*, 1983; Immel, 1991). In addition, no signs of toxicity or macroscopic changes related to the oral administration of γ-cyclodextrin were observed in any of the animals administered γ-cyclodextrin in these studies (Matsuda *et al.*, 1983; Immel, 1991).

IV.D.2 Repeated Dose Studies

No traditional toxicological studies have been performed to assess the short- or long-term safety of cyclic dextrin, highly branched as it is expected that the safety of the ingredient would be equivalent to that of other dietary α-glucans, including hydrolyzed starch, based on the readily degradable nature of the ingredient to glucose by normal digestive processes. Moreover, considering that the only absorbable product of α-glucan digestion is glucose, the intact highly-branched cyclic dextrin molecules and any incompletely digested material thereof would not be systemically absorbed. Thus, cyclic dextrin, highly branched itself would not produce any systemic toxicological effects following oral consumption. Furthermore, the low toxicity of large-ring cyclic α-glucans following oral exposure is supported by the results of a number of studies examining the potential oral toxicity of γ-cyclodextrin in rats and dogs (Lina and Bär, 1998; Til and Bär, 1998; Lina, 1999). These studies are discussed below and are summarized in Table IV.D.2-1.

In a rat study reported by Lina and Bär (1998), male Wistar rats (5/group) were fed diets containing 0 (control), 5, 10, 15, or 20% γ-cyclodextrin, equivalent to 3.3, 6.6, 9.9, and 11.4 g/kg body weight/day, respectively, during a 2-week pilot study. In the subsequent subchronic study, male and female rats (20/sex/group) were fed diets containing γ-cyclodextrin at levels of 0 (control), 1.5, 5, or 20%, equivalent to doses of 0, 0.86, 2.9, and 11.4 g/kg body weight/day for males and 0, 0.97, 3.3, and 12.7 g/kg body weight/day for females, respectively, for a period of 13 weeks. Dietary levels of γ-cyclodextrin of up to 20% produced physiological responses that were consistent with ingestion of high levels of incompletely digested carbohydrates and were further considered not to be a safety concern for humans (Bär, 1985; Newberne *et al.*, 1988). Such effects included soft stools, a significant decrease in food intake (2-week pilot study only), a significant, yet slight, reduction in body weight (males only), and significant enlargement of the full and empty cecum (males only) compared to control groups. Similar effects also were observed upon administration of a diet consisting of 20% lactose, a carbohydrate that is incompletely digested in the small intestine of rats (Dahlqvist and Thomson, 1964).

Rats provided γ-cyclodextrin in the subchronic study also displayed other variations, including significant increases in relative liver, brain, and adrenal weights, significantly elevated levels of plasma alkaline phosphatase (ALP) and aspartate aminotransferase (AST) activities, and

changes in certain hematological parameters that attained statistical significance compared to control rats (Lina and Bär, 1998). However, these changes were small in magnitude, not dose-dependent, occurred in 1 sex only, and/or were observed only at the end of the recovery period. In addition, increases in plasma ALP and AST activity levels were not accompanied by changes in the levels of other indicators of hepatotoxicity. Moreover, all changes observed in γ-cyclodextrin-fed rats were not accompanied by any compound-related macroscopic or histopathological abnormalities. Accordingly, the changes in organ weights and clinical and hematological parameters were considered to be not toxicologically significant.

Physiological responses observed in rats also were observed in dogs administered γ-cyclodextrin at comparable dietary levels (up to 20%) (Til and Bär, 1998). In this study, Beagle dogs were fed diets containing γ-cyclodextrin at levels of 0 (control), 5, 10, or 20%, equivalent to doses of 0, 2.0, 3.8, and 7.7 g/kg body weight/day for males and 0, 2.0, 4.0, and 8.3 g/kg body weight/day for females, respectively, for 13 weeks. A dose-dependent increase in the incidence and severity of transient diarrhea and a non-significant reduction in body weight gain was observed in males of the 20% γ-cyclodextrin group compared to control males. Significant organ weight changes included increases in ovary weights, male liver weights, and female empty cecum weights at the 10 and 20% γ-cyclodextrin dietary levels compared to control groups. However, no compound-related gross or histopathological findings were observed in these or in any other organs examined. Additionally, the increase in liver weight in males was not associated with changes in plasma levels of any indicators of hepatotoxicity. Furthermore, contributing factors to the increases in relative liver and ovary weights were the observed reductions in body weight gain in high-dose males and atypically low ovary weights of control females, respectively. Therefore, these organ weight alterations were not related to the administration of γ-cyclodextrin in the diet and were deemed by the authors to be of no toxicological significance. Based on the results of these studies, 20%, the highest dietary concentration tested, was established as the no-observed-adverse-effect level (NOAEL) for γ-cyclodextrin, equivalent to approximately 11 and 13 g/kg body weight/day for male and female Wistar rats, respectively (Lina and Bär, 1998), and approximately 8 g/kg body weight/day for male and female Beagle dogs (Til and Bär, 1998).

Results similar to those observed in subchronic toxicity studies were reported in a 1-year chronic toxicity study (Lina, 1999) that was reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1999) and Munro *et al.* (2004). Groups of Wistar rats (20/sex/treatment group) were fed diets containing 0, 5, 10, or 20% γ-cyclodextrin (approximately 8.7 and 10.8 g/kg body weight/day in males and females at the highest concentration, respectively). Mortality, general condition and behavior, food intake, body weights, ophthalmoscopic observations, hematology and urinalysis results, and plasma and urinary electrolyte levels were similar between γ-cyclodextrin and control groups. Compared to the control group, statistically significant, yet marginal increases in plasma levels of ALP, alanine aminotransferase (ALT), and ornithine carbamoyl transferase activities occurred at

Week 14 and/or Week 26 in the high-dose (20%) group. However, these alterations were transient and not accompanied by histopathological abnormalities in the liver, and thus, were considered not to be toxicologically relevant. A significant, yet transient, increase in plasma creatinine concentration also was observed in females of the 10 and 20% groups at Week 14 and/or Week 26. In males and females of the high-dose group (20%), a significant decrease in plasma phospholipid levels was observed only at Week 14. Plasma triglyceride levels also were significantly decreased in males of the high-dose group (20%) at Week 14. Relative organ weights were unaffected by γ-cyclodextrin feeding, except in the high-dose group in which the cecum of male rats was significantly, yet slightly, enlarged and relative testis weights significantly increased compared to the control group. These organ weight changes, however, were not accompanied by any compound-related macroscopic or histopathological abnormalities. Based on the results of this study, the NOAEL for γ-cyclodextrin was set at 20% in the diet, the highest dose tested, which was equivalent to approximately 9 and 11 g/kg body weight/day for male and female Wistar rats, respectively.

Collectively, the results of these studies suggest that γ-cyclodextrin, when consumed at high doses, is not completely digested in the small intestine and that a small portion of the compound may reach the large intestine. Incomplete digestion of γ-cyclodextrin, however, is not of toxicological concern, because, as with other incompletely absorbed carbohydrates (*i.e.*, starch), the non-digested fraction passes into the colon for further degradation by intestinal microflora. Similar effects may be expected with the cyclic dextrin, highly branched ingredient; however, cyclic dextrin, highly branched is likely completed digested in humans following consumption based on the results of a human study (Takii *et al.*, 2004; discussed in Section IV.E.1), and considering that the daily intakes of cyclic dextrin, highly branched are resultant of smaller intakes throughout the day and not due to large bolus intakes. Furthermore, these data support the low toxicity of relatively large-ring cyclic α-glucans following repeated exposure. Thus, no adverse effects are expected to be associated with the large-ring cyclic α-glucan moiety of cyclic dextrin, highly branched following repeated oral exposure.

Table IV.D.2.2-1 Summary of Subchronic and Chronic Toxicity Studies on γ-Cyclodextrin

Species (Strain; N)	Study Duration	Route of Administration	Concentration/Dose	Reported Effects [a, b, c]		Reference
Pilot study: Rat (Wistar; 5 M/group)	Pilot study: 2 week	Oral (diet)	Concentration: 0 (control), 5, 10, 15, or 20% Equivalent dose: 0, 3.3, 6.6, 9.9, and 11.4 g/kg bw/d Positive control: 20% lactose	General condition/ survival	No mortalities and γ-CD generally well-tolerated at all doses Soft stools [Positive control, ≥10%], but no laxation	Lina and Bär, 1998
				Food and water intake	↓ Food intake [Positive control and all γ-CD groups] No effects on food efficiency and water intake	
				Body weight	NR	
				Organ and tissue effects	↑ Full and empty cecum weights [≥5%] No effects on liver and kidney weights No compound-related gross lesions	
				Hematology, clinical chemistry, and urinalysis	↑ ALP levels [20%] ↓ GGT levels [≥5%]	
				NOAEL	20% in diet or 11.4 g/kg bw/d[d]	
Full study: Rat (Wistar; 20/sex/group except 10/sex/group for satellite groups)	Full study: 13 weeks + 4-week recovery period (for satellite groups only)		Concentration: 0 (control), 1.5, 5, or 20%[e] Equivalent dose: M: 0, 0.86, 2.9 and 11.4 g/kg bw/d F: 0, 0.97, 3.3 or 12.7 g/kg bw/d Positive control: 20% lactose Satellite groups: Concentration: 0 (control), or 20% Equivalent dose: M – 0 or 11.4 g/kg bw/d F – 0 or 12.7 g/kg bw/d	General condition/ survival	Soft stools [Positive control, ≥5%] Transient diarrhea [Positive control]	
				Food and water intake	No significant compound-related changes in food intake, food efficiency, or water intake	
				Body weight	↓ Body weights [M; Positive control, 20%]	
				Organ and tissue effects	↑ Relative liver weight [M; 20%] ↑ Relative brain weight [M; Positive control, 20%] ↑ Relative adrenal weights [M; 20%] ↑ Relative full cecum weights in [M; 20%] ↓ Empty cecum weights [F; 20%] No significant compound-related changes in macro- or microscopic findings	
				Hematology, clinical chemistry, and urinalysis	↑ AST [F; 20%] No significant compound-related changes in hematology, urine and fecal analysis, or other clinical chemistry parameters	

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Table IV.D.2.2-1 Summary of Subchronic and Chronic Toxicity Studies on γ-Cyclodextrin

Species (Strain; N)	Study Duration	Route of Administration	Concentration/Dose	Reported Effects [a, b, c]		Reference
			Positive control: 20% lactose	NOAEL	20% in diet or 11.4 g/kg bw/d (M) and 12.7 g/kg bw/d (F) [d]	
Rat (Wistar, 20/sex/group)	1 year	Oral (diet)	Concentration: 0 (control), 5, 10 or 20% Equivalent dose: M: 0, 2.1, 4.3, or 8.7g/kg bw/d F: 0, 2.7. 5.4, or 10.8 g/kg bw/d	General condition/ survival	No significant compound-related changes in mortality, general condition and behavior, or ophthalmology findings	Lina, 1999
				Food and water intake	No significant compound-related changes in food intake, food efficiency, or water intake	
				Body weight	No significant compound-related changes in body weights	
				Organ and tissue effects	↑ Absolute and relative cecum and relative testis weights [M; 20%] No significant compound-related changes in macro- or microscopic findings	
				Hematology, clinical chemistry, and urinalysis	↑ ALP activity [20%] ↑ ALT and OCT activities [M; 20%]; transient ↓ TG [M; 20%]; transient ↓ PL [20%]; transient ↑ creatinine [F; 20%]; transient No significant compound-related changes in hematology or urinalysis findings	
				NOAEL	20% in diet or 8.7g/kg bw/d (M) and 10.8 g/kg bw/d (F) [d]	
Dog (Beagle; 4/sex/group)	13 weeks	Oral (diet)	Concentration: 0 (control), 5, 10, or 20% Equivalent dose: M: 0, 2.0, 3.8, and 7.7 g/kg bw/d F: 0, 2.0, 4.0, and 8.3 g/kg bw/d	General condition/ survival	No mortalities and γ-CD generally well-tolerated at all doses Transient diarrhea at all doses; dose-dependent increase in incidence and severity No significant compound-related changes in behavior, appearance, or ophthalmology findings	Til and Bär, 1998
				Food and water intake	No significant compound-related changes in food intake and food efficiency	

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Table IV.D.2.2-1 Summary of Subchronic and Chronic Toxicity Studies on γ-Cyclodextrin

Species (Strain; N)	Study Duration	Route of Administration	Concentration/Dose	Reported Effects [a, b, c]		Reference
				Body weight	↓ Body weight gain during the last 6 weeks (NS) [M; 20%]	
				Organ and tissue effects	↑ Absolute and relative ovary weights [F; ≥10%]; due to low ovary weights in control group ↑ Relative liver weight [M; ≥10%] ↑ Absolute and relative empty cecum weights [F; ≥10%] No significant compound-related changes in macro- or microscopic findings	
				Hematology, clinical chemistry, and urinalysis	No significant compound-related changes in clinical chemistry, hematology, or urinalysis findings	
				NOAEL	20% in diet or 7.7 g/kg bw/d (M) and 8.3 g/kg bw/d (F) [d]	

↓ = decreased; ↑ = increased; γ-CD = γ-cyclodextrin; ALP = alkaline phosphatase; ALT = alanine aminotransferase; AST = aspartate aminotransferase; bw = body weight; d = day; F = female; GGT = *gamma* glutamyltransferase; M = male; NOAEL = no-observed-adverse-effect level; NS = non-significant; OCT = ornithine carbamoyl transferase; PL = phospholipids; TG = triglycerides

[a] As reported by the authors.

[b] Numbers in [ ] correspond to the γ-CD dose(s) at which the reported effects were observed.

[c] Unless otherwise stated, all reported effects are statistically significant and relative to the control group.

[d] Value reported by authors.

[e] After 2 months of treatment, rats in 20% γ-CD erroneously received 20% lactose for 2 weeks due to mislabeling of the test diet. Consequently, diets were corrected and the study was repeated.

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IV.D.3 Developmental Toxicity Studies

As with the repeated-dose toxicity studies, developmental and reproductive toxicity studies on cyclic dextrin, highly branched have not been performed and were not considered necessary as the ingredient is completely digested to glucose, a safe product of normal carbohydrate digestion. In addition, developmental toxicity studies on γ-cyclodextrin conducted in Wistar rats and New Zealand White rabbits support the low developmental toxicity of cyclic α-glucans (Waalkens-Berendsen *et al.*, 1998a,b). These studies are discussed below and are summarized in Table IV.D.3-1.

In the developmental toxicity study conducted in Wistar rats, dams were fed diets containing 0 (control), 1.5, 5, 10, or 20% γ-cyclodextrin (approximately 0, 0.85 to 0.97, 2.8 to 3.1, 5.6 to 6.2, and 10.7 to 11.8 g/kg body weight/day, respectively) from Gestation Days 0 to 21 (Waalkens-Berendsen *et al.*, 1998a). The same group of investigators also conducted a similar study in New Zealand rabbits, in which dams were administered γ-cyclodextrin in the diet at levels of 0 (control), 5, 10, or 20% (approximately 0, 1.6 to 2.1, 3.1 to 4.2, and 4.9 to 7 g/kg body weight/day, respectively) from Gestation Days 0 to 29 (Waalkens-Berendsen *et al.*, 1998b). In both studies, the animals were killed on the last day of administration and the fetuses were removed for examination. Study results indicate that γ-cyclodextrin at dietary levels of up to 20% was well-tolerated by dams and did not cause any compound-related maternal adverse effects or deaths in rats and rabbits (Waalkens-Berendsen *et al.*, 1998a,b). In addition, administration of γ-cyclodextrin did not adversely affect the following in either species: gravid or empty uterus weights, ovary weights, placenta weights, corpora lutea, implantation sites, pre/post-implantation loss, the number of live fetuses, the mean number of early/late resorptions, or sex ratios (Waalkens-Berendsen *et al.*, 1998a,b). In fetal rats, microscopic examination revealed no compound-related external, visceral, or skeletal malformations or anomalies in any of the γ-cyclodextrin groups or the control group (Waalkens-Berendsen *et al.*, 1998a). The increases in the incidence of stomach hypertrophy (at 5 and 10% γ-cyclodextrin) and in total and individual skeletal variations (crooked toes in hindlimbs at 1.5 and 5% γ-cyclodextrin) observed in γ-cyclodextrin-exposed fetal rats compared to control fetuses were not dose-dependent, and thus, were considered not to be related to γ-cyclodextrin exposure (Waalkens-Berendsen *et al.*, 1998a). In fetal rabbits whose dams were exposed to 5 or 20% γ-cyclodextrin, an increase in the incidence of hemorrhagic fluid in the abdominal cavity was observed compared to control fetuses (Waalkens-Berendsen *et al.*, 1998b). This effect was not dose-dependent and also was observed to a similar extent in lactose-exposed fetuses. The authors attributed this visceral anomaly to an artifact produced from the method of preservation of the fetus at -20°C. Microscopic examination of the rabbit fetuses revealed no other significant increases in external, visceral, or skeletal malformations, anomalies, or variations between any of the γ-cyclodextrin groups and the control group (Waalkens-Berendsen *et al.*, 1998b).

The results of these studies indicate that orally administered γ-cyclodextrin at levels up to 20% in the diet (approximately 11 g/kg body weight/day for rats and 5 to 7 g/kg body weight/day for

rabbits) is not maternally toxic in rats or rabbits. The study results also indicate that *in utero* exposure to γ-cyclodextrin at levels of up to 20% of the maternal diet, equivalent to a dose of approximately 11 g/kg body weight/day in rats and 5 to 7 g/kg body weight/day in rabbits, is not associated with embryotoxicity, fetotoxicity, or teratogenicity in Wistar rats or New Zealand White rabbits. From these data, consumption of large-ring cyclic α-glucans would not be associated with developmental toxicity. Therefore, no adverse effects on development are expected to be associated with the large-ring cyclic α-glucan moiety of cyclic dextrin, highly branched.

Table IV.D.3-1 Summary of Developmental Toxicity Studies on γ-Cyclodextrin

Species	Duration	Route	Concentration/Dose	Reported Effects[a, b]		Reference
Rat (Wistar Crl:(WI)WU BR; 16-23 dams/ group)	GD 0 to 21	Maternal: Oral (diet) Fetuses: *in utero*	Concentration: 0 (control), 1.5, 5, 10, or 20% Equivalent dose: 0, 0.85-0.97, 2.8-3.1, 5.6-6.2, and 10.7-11.8 g/kg bw/d Positive control: 20% lactose	Maternal Effects	No mortalities and no signs of ill health, abnormal behavior, or GI intolerance, and γ-CD generally well-tolerated at all doses ↓ Food intake from GD 0-16 [20%] No compound-related macroscopic findings at necropsy No significant differences in body weight, weight gain, gravid or empty uterus weights, ovary weights, placenta weight, corpora lutea, implantation sites, pre/post-implantation loss, the number of live fetuses, mean number of early/late resorptions, or sex ratios No abortions or pre-mature deliveries	Waalkens-Berendsen *et al.*, 1998a
				Fetal Effects	No significant difference in fetal weight or length No significant difference in total visceral variations, but ↑ hypertrophy in stomach [5 and 10%] ↑ Total skeletal variations [5%] ↑ crooked toes in hindlimbs [1.5, 5%] No compound-related external, visceral, skeletal malformations or anomalies	
				NOAEL	20% in maternal diet or 11 g/kg bw/d	
Rabbit (New Zealand White; 11-15 dams/group)	GD 0 to 29	Maternal: Oral (diet) Fetuses: *in utero*	Concentration: 0 (control), 5, 10, or 20% Equivalent dose: 0, 1.6-2.1, 3.1-4.2, and 4.9-7 g/kg bw/d Positive control: 20% lactose	Maternal Effects	No mortalities and no signs of ill health or abnormal behavior and γ-CD generally well-tolerated Transient diarrhea in few animals during first few days [10 and 20%] ↓ Weight gain and food intake from GD 0 to 6 [20%] No compound-related macroscopic findings at necropsy No significant differences in body weights, gravid or empty uterus weights, ovary weights, placenta weight, corpora lutea, implantation sites, pre/post-implantation loss, the number of live fetuses, mean number of early/late resorptions, or sex ratios No significant differences in abortions or pre-mature deliveries	Waalkens-Berendsen *et al.*, 1998b

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Table IV.D.3-1 Summary of Developmental Toxicity Studies on γ-Cyclodextrin

Species	Duration	Route	Concentration/Dose	Reported Effects[a, b]		Reference
				Fetal Effects	No significant difference in fetal weight or length ↑ Incidence of hemorrhagic fluid in abdominal cavity [Positive control, 5 and 20%] No compound-related external, visceral, skeletal malformations, anomalies, or variations	
				NOAEL	20% in maternal diet or 5 g/kg bw/d	

↓ = decreased; ↑ = increased; γ-CD = γ-cyclodextrin; bw = body weight; d = day; GD = gestational day; NOAEL = no-observed-adverse-effect level
[a] Numbers in [ ] correspond to the γ-CD dose(s) at which the reported effects were observed.
[b] Unless otherwise stated, all reported effects are statistically significant and relative to the control group.

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IV.D.4 Mutagenicity and Genotoxicity Studies

IV.D.4.1 *In Vitro* Studies

Cyclic dextrin, highly branched was shown to be non-mutagenic in the Ames reverse mutation assay (Choi *et al.*, 2009). The assay was conducted using a battery of 4 standard *Salmonella typhimurium* tester strains (TA98, TA100, TA1535, and TA1537), as well as 1 *Escherichia coli* tester strain (WP2*uvr*A). Bacterial strains were treated with cyclic dextrin, highly branched at concentrations of 156, 313, 625, 1,250, 2,500, or 5,000 µg/plate. Assays were conducted in the presence or absence of rat liver microsomal S9 metabolic activation. Water vehicle served as a negative control for all strains. The following compounds were employed as positive controls for the assay conducted in the absence of metabolic activation: 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide (AF-2), sodium azide, 9-aminoacridine (9AA), and 2-aminoanthracene (2-AA). For the assay conducted in the presence of metabolic activation, 2-AA was employed as the positive control. Cyclic dextrin, highly branched was not cytotoxic to any bacterial strain and the mean number of revertant colonies following cyclic dextrin, highly branched treatment was comparable to that of the negative control in all strains and at all concentrations tested in either the absence or presence of S9 metabolic activation. Thus, cyclic dextrin, highly branched is considered to be non-mutagenic.

The non-mutagenicity of large-ring cyclic α-glucans is supported by the negative results obtained in an Ames assay conducted in *S. typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA100 with γ-cyclodextrin at concentrations of up to 20 mg/plate (Blijleven, 1991). Negative results for clastogenicity also were obtained in human lymphocytes exposed to γ-cyclodextrin at concentrations of up to 5,000 µg/mL (de Vogel and van Delft, 1996).

IV.D.4.2 *In Vivo* Studies

The potential genotoxicity of cyclic dextrin, highly branched was not assessed *in vivo*; however, a micronucleus assay involving oral administration of mice with γ-cyclodextrin was identified in the JECFA evaluation of γ-cyclodextrin (Immel, 1991). Groups of Swiss mice (15/sex) were administered single gavage doses of 15 g/kg body weight of γ-cyclodextrin and were terminated in groups of 5 males and 5 females at 24, 48, and 72 hours. The bone marrow was assessed for micronucleus formation. The assay yielded negative results.

IV.E Studies in Humans

IV.E.1 Cyclic Dextrin, Highly Branched

The tolerability of the cyclic dextrin, highly branched ingredient in humans was examined in a study by Takii *et al.* (2004). Takii *et al.* (2004) studied the differential effects between a commercial dextrin of a dextrose equivalent 16 (DE16) and a cyclic dextrin, highly branched-based sports drink on GI disturbances (*e.g.*, belching, flatulence, nausea) during exercise. The study was conducted in 7 untrained male subjects (34.3±2.8 years old). Study participants were

provided water or a prototype sports drink containing cyclic dextrin, highly branched, DE16, or glucose, with several days between each trial. Each carbohydrate-based drink (350 mL) was composed of 10% carbohydrates, providing approximately 35 g of carbohydrate person. The subjects consumed the drinks immediately after completing 3 minutes of cycling, after which they were permitted a 10-minute rest. The subjects then completed a further 30 minutes of cycling. Every 5 minutes after drinking the test drinks, the subjects were asked to assess feelings of flatulence up to the end of the cycling period (40 minutes after drink consumption). The frequency of belching also was recorded. The cyclic dextrin, highly branched-based sports drink produced significantly lower flatulence scores and significantly fewer incidences of belching during exercise compared to the other test drinks (DE16 and glucose). Incidence of these GI effects following cyclic dextrin, highly branched consumption was similar to that observed with water. The results of this study demonstrate that cyclic dextrin, highly branched is well-tolerated following consumption by humans.

The same authors also investigated the effect of a single dose of cyclic dextrin, highly branched on gastric emptying time (GET) in comparison to other carbohydrate solutions in humans (Takii *et al.,* 2005). Ten (10) healthy volunteers (7 men and 3 women) were provided with 350 mL of test solution, containing cyclic dextrin, highly branched or glucose, to consume within 2 minutes. First, a dose-response experiment was conducted in which subjects consumed solutions containing either cyclic dextrin, highly branched or glucose at concentrations of 1.25, 2.5, 5, or 10%. In a second set of experiments, subjects consumed test drinks composed of water, physiological saline, or carbohydrate solution containing cyclic dextrin, highly branched, commercially available DE16, glucose, maltose, or sucrose. The test solutions provided either 17.5 g (5%) or 35 g (10%) of carbohydrate/ person. While the authors did not explicitly indicate that GI side effects were monitored during the course of the study, no incidence of any GI symptoms were noted by the authors.

IV.E.2 γ-Cyclodextrin

Koutsou *et al.* (1999) conducted a randomized, double-blind, cross-over (1-week wash-out period) study to assess the tolerability of γ-cyclodextrin in comparison to that of maltodextrin. The study included 24 apparently healthy male (n=12) and female (n=12) students, 21 to 24 years of age. On the day of the trial, groups of 12 study participants were provided 8 grams of either maltodextrin or γ-cyclodextrin mixed in 100 g of yogurt to be consumed within 15 minutes as a mid-morning snack. Subjects were required to record and score GI tolerance symptoms (belching, nausea, vomiting, bloating, borborygmia, abdominal cramping, and flatulence) at 3 to 4 and 7 to 8 hours following maltodextrin or γ-cyclodextrin consumption. Subjects also were required to record the number and time of defecations, as well as the consistency of feces (watery, normal, or hard). Three (3) to 4 hours after maltodextrin consumption, 5 subjects reported a total of 12 symptoms, including 3 cases of nausea, 2 cases each of belching, bloating, and watery feces, and 1 case of borborygmia. The grade of severity of GI symptoms ranged from 1 (more than normal) to 3 (exceptionally more than normal), depending on the

case. In addition, 1 mild case (grade 1) of flatus was recorded 7 to 8 hours after maltodextrin consumption. Following γ-cyclodextrin consumption, all GI symptoms experienced by subjects were mild in nature (grade 1) and occurred during the first 3 to 4 hours except for 1 mild case of watery feces, which was reported 7 to 8 hours after γ-cyclodextrin consumption. Specifically, 5 subjects reported a total of 6 symptoms following γ-cyclodextrin consumption, including 2 cases of flatus and 1 case each of borborygmia, abdominal cramping, and watery feces. Statistical analyses revealed no significant difference in the incidence of GI symptoms between subjects consuming maltodextrin or γ-cyclodextrin when the symptoms were analyzed individually or in combination. None of the subjects complained of vomiting or diarrhea. Thus, a single dose of 8 g γ-cyclodextrin was shown to be well-tolerated by humans and did not result in GI discomfort.

The study evaluating the effect of γ-cyclodextrin on postprandial glycemic response described in Section IV.C.1 also included an assessment of tolerance (Asp *et al.*, 2006). In total, 32 healthy male (n=11) and non-pregnant, non-lactating female (n=21) subjects, 21 to 36 years of age, participated in this randomized, double-blind, cross-over trial. Subjects were provided with 50 g of either γ-cyclodextrin or maltodextrin served in a 480 mL beverage for oral consumption following an overnight fast. The frequency and severity of GI tolerance symptoms were recorded for the first and second 24-hour periods following test beverage consumption. Symptoms of nausea, abdominal cramping, abdominal distention, and flatulence were scored for frequency (0 = usual, 10 = more than usual) and severity (0 = absent, 10 = severe). Stool frequency and consistency information also was collected for the first and second 24-hour periods following test beverage consumption. Subjects recorded the time of each bowel movement and stool consistency, which was scored using a 5-point scale. Results for γ-cyclodextrin were compared to those of maltodextrin. Both carbohydrate beverages were well-tolerated by subjects. The mean severity rankings for all GI symptoms following both γ-cyclodextrin and maltodextrin administration were <2 and <1 for the first and second 24-hour periods, respectively. Similar results were observed for the frequency scores. The mean rankings for stool consistency and frequency were 2.41 and 1.03, respectively, and were not significantly different from those obtained after maltodextrin consumption. Thus, a single dose of 50 g of γ-cyclodextrin was well-tolerated and did not result in adverse GI effects. The results of this study corroborate those of Koutsou *et al.* (1999), with both studies demonstrating good tolerability of γ-cyclodextrin at doses of up to 50 g in humans.

IV.F Additional Safety-Related Considerations

IV.F.1 Potential Effects on Nutrient Absorption

Due to the steric arrangement of the glucose units of cyclodextrins, which ensures that the inner side of the molecule is less polar than the outer side, cyclodextrins have the ability to form inclusion complexes with various organic compounds, including fat-soluble vitamins and polyunsaturated fatty acids (Munro *et al.*, 2004). As a result of this property, the possibility of an interaction between cyclodextrins and nutrients was considered as part of the safety

assessment of γ-cyclodextrin by Munro *et al.* (2004). Munro *et al.* (2004) argued that the formation of inclusion complexes is reversible and that in the presence of other food components or contents of the stomach or intestine, vitamins complexed with cyclodextrins would be replaced by other organic compounds of greater affinity. Along the same lines, cyclodextrins have been shown to increase the bioavailability of fat-soluble vitamins and other lipophilic compounds by increasing the water solubility of these compounds through formation of inclusion complexes (Szejtli *et al.*, 1983; Bárdos *et al.*, 1989; Cravatto *et al.*, 2006). This property of cyclodextrins enhances the dissolution of normally hydrophobic compounds in the GI tract upon oral ingestion, ultimately increasing their availability for absorption. Moreover, following ingestion, γ-cyclodextrin is subject to complete hydrolysis beginning in the mouth *via* the action of salivary α-amylase and continuing in the intestine. Further support for the absence of a cyclodextrin-related effect on nutrient absorption was derived from a 1-year dog study conducted with β-cyclodextrin in which no effects were observed on plasma and liver levels of vitamins A and E, and plasma levels of vitamin D (hepatic vitamin D levels were not assessed) following administration of β-cyclodextrin in the diet at concentrations of up to 5% (Bellringer *et al.*, 1995; Toyoda *et al.*, 1997).

Since cyclic dextrin, highly branched comprises highly-branched cyclic dextrin molecules, the possibility of an interaction between nutrients and the cyclic α-glucan moiety of these molecules also was considered; however, there are no existing data to suggest that the cyclic portion of highly-branched cyclic dextrin molecules forms complexes with organic compounds. Inclusion properties of the smaller cyclodextrins are driven by the steric forces associated with the glucose molecules joining to form a small ring. Given that the cyclic structures of the ingredient comprise at least 16 glucose molecules and as many as 100, the steric arrangement, particularly of the larger cyclic structures, would not be expected to be similar to that of a small cyclodextrin, but would instead allow for flexibility and conformational freedom. Thus, the cyclic moieties of the highly-branched cyclic dextrin molecules would be less likely to form inclusion complexes with nutrients. Furthermore, ring size is an important determinant of the hydrolysis of cyclic molecules, with the rate of hydrolysis increasing with increasing ring size. Accordingly, the cyclic moieties of the highly-branched cyclic dextrin molecules will be hydrolyzed rapidly, thus creating less potential for interaction with nutrients following oral consumption.

IV.F.2 Potential Effects on Cell Membranes

In vitro, cyclodextrins have been shown to induce hemolysis of erythrocytes likely as a result of cyclodextrin-mediated extraction of cholesterol and other lipids from the membrane of red blood cells (Irie *et al.*, 1982). In comparison to α- and β-cyclodextrin, γ-cyclodextrin possessed the lowest effect on membranes (Okada *et al.*, 1988; Yoshida *et al.*, 1988; Ohtani *et al.*, 1989; Bar and Ulitzur, 1994; Leroy-Lechat *et al.*, 1994). Considering that the highly-branched cyclic dextrin molecules also contain a cyclic α-glucan structure, the possibility of cyclic dextrin, highly branched-induced hemolysis was assessed. However, as previously mentioned, in light of the considerably larger size of the ring moieties of the highly-branched cyclic dextrin molecules

compared to the cyclodextrins, it is not likely that the cyclic dextrin, highly branched ingredient would share similar hemolytic properties. More importantly, however, the highly-branched cyclic dextrin molecules are hydrolyzed following ingestion and not absorbed intact, and therefore, are unlikely to have any effect on erythrocytes.

IV.F.3 Gastric Emptying Time (GET)

Some substances, including ethanol and certain drugs (*e.g.*, aspirin), are metabolized to some extent in the stomach (Seitz and Pöschl, 1997; Caballería, 2003). Thus, changes in GET may have an effect on the metabolism of such substances. In the human study by Takii *et al.* (2005) discussed in greater detail in Section IV.E.1, GET was assessed following consumption of a 5 or 10% cyclic dextrin, highly branched solution and compared to that following consumption of solutions prepared with other carbohydrates (5 or 10% glucose, maltose, sucrose, and DE16). No significant differences were observed in GET following ingestion of any of the 5% carbohydrate solutions. However, 10% solutions of glucose and maltose were shown to result in longer (statistically significant in the case of glucose) GET compared to a 10% cyclic dextrin, highly branched solution. Conversely, GET following ingestion of the 10% cyclic dextrin, highly branched solution was longer compared to that following ingestion of sucrose- or dextrin (DE16)-based solutions. While the 10% cyclic dextrin, highly branched solution was evacuated faster from the stomach than either a solution of glucose or maltose, its GET was generally within the range of the other commonly consumed carbohydrates tested in this study. In a sports drink, containing minerals, vitamins, and organic acids, cyclic dextrin, highly branched displayed a faster GET than DE16, indicating that the presence of other substances affects GET. In a mixed food matrix, fats and protein will have a greater effect on GET than carbohydrates. Thus, while cyclic dextrin, highly branched has some effect on GET, its GET is comparable to that of other carbohydrates. Furthermore, given that many of the intended uses of cyclic dextrin, highly branched are in foods containing other nutrients, consumption of cyclic dextrin, highly branched is not expected to have any physiologically significant effect on GET, and consequently, on the metabolism of substances that are metabolized in the stomach.

IV.G Summary and Basis for GRAS Conclusion

The GRAS determination for the use of cyclic dextrin, highly branched as a food ingredient is based on scientific procedures. The ingredient is composed of not less than 80% highly-branched cyclic dextrin molecules, with the remainder of the ingredient composed of moisture and ash (<6%), glucose (<3.5%), and other saccharide molecules (approximately 10%) with molecular weights outside the range of the highly-branched cyclic dextrins. Cyclic dextrin, highly branched is intended for use in a variety of traditional food products, including baked goods and baking mixes, beverages and beverage bases, breakfast cereals, tea, grain products, seasonings, milk and plant protein products, processed fruits and vegetables and fruit and vegetable juices, soft candy, and powdered soups. Cyclic dextrin, highly branched will be added to selected ready to eat foods and beverages at maximum use levels of up to 30%. In

products requiring further preparation prior to consumption (*i.e.*, beverage powders, powdered seasonings, and dry soup mixes), the ingredient will be added at maximum use levels of up to 75%. The resulting cyclic dextrin, highly branched levels will range from 0.25 to 24 g per RACC (21 CFR 101.12 – U.S. FDA, 2009). Under the intended conditions of use, the estimated all-user mean and 90th percentile intakes of cyclic dextrin, highly branched by the total U.S. population are 22 g/person/day (425 mg/kg body weight/day) and 48 g/person/day (1,011 mg/kg body weight/day), respectively.

Cyclic dextrin, highly branched is produced in accordance with cGMP and meets appropriate food-grade specifications. The ingredient is produced from a GRAS substance, consisting of food-grade waxy corn starch (unmodified). The manufacture of cyclic dextrin, highly branched involves hydrolysis of the waxy corn starch starting material using α-amylase derived from non-genetically modified *B. subtilis*. *B. subtilis*-derived carbohydrase preparations containing α-amylase are affirmed as GRAS by FDA for use as direct food substances. Subsequently, bacterially-derived 1,4-α-D-glucan branching enzyme [(1→4)-α-D-glucan:(1→4)-α-D-glucan 6-α-D-[(1→4)-α-D-glucano]-transferase); EC 2.4.1.18; CAS No. 9001-97-2] is applied to the hydrolyzed waxy corn starch and catalyzes a cyclization reaction within the oligosaccharide clusters (intramolecular transglycosylation). The end product is a highly-branched cyclic dextrin molecule, in which the structural units consist of α-D-glucose monomers linked by α-(1,4) glucosidic bonds, with branching and cyclization occurring *via* α-(1,6) glucosidic bonds. The branching enzyme is derived either from non-genetically modified *B. stearothermophilus* TRBE14 or genetically-modified *B. subtilis* 168 and is a safe and suitable enzyme for the production of cyclic dextrin, highly branched[2]. It should be noted that the bacteria used to produce the branching enzyme preparation are lysed and removed from the branching enzyme preparation at the enzyme production stage, and therefore, the bacteria are not carried over into the final product. Carry-over of active enzyme residues is prevented by denaturing and inactivating the enzyme *via* pH reduction and high-temperature heating immediately following each enzyme-catalyzed reaction. Downstream steps in the manufacturing process for cyclic dextrin, highly branched include filtration, decolorization, and deionization to remove the biocatalysts and any residual particles. Lot samples are routinely assayed to verify compliance with the specifications, including those for chemical impurities and microbiological contaminants, and non-consecutive batch analyses confirm the consistency of the final product and reproducibility of the manufacturing process. Additional analyses for pesticides and mycotoxins indicate compliance of the waxy corn starch starting material with current FDA action levels.

The safety of cyclic dextrin, highly branched under the intended conditions of use is supported by the digestibility of the ingredient and the available ingredient-specific toxicological and human

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[2] A GRAS Exemption claim for 1,4-α-D-glucan branching enzyme derived from non-genetically modified *B. stearothermophilus* strain TRBE14 and genetically-modified *B. subtilis* strain 168 has been concurrently submitted to FDA.

studies. The safety data from metabolism studies and toxicity and human studies conducted with cyclic dextrin, highly branched are corroborated by toxicological and human data on γ-cyclodextrin, which is the largest cyclodextrin [*i.e.*, cyclic α-(1-4) glucan] currently permitted for use in food in the U.S. Although cyclic dextrin, highly branched and γ-cyclodextrin are not structurally identical, their cyclic structures, although also not identical, share similarities in that both are cyclic α-glucans with a common metabolic fate. Thus, toxicological studies on γ-cyclodextrin were considered to be appropriate for discussing the safety of the cyclic α-glucan moiety of the highly branched cyclic dextrin molecules. The branched clusters of the highly-branched cyclic dextrin molecules are derived from amylopectin, and thus, do not pose a safety concern considering that starch components possess a long history of safe consumption in humans. The safety of the ingredient also is supported by the long history of safe use of modified food starches in food.

Cyclic dextrin, highly branched consists of hydrolyzed amylopectin, a component of starch, with further enzymatic modification to produce a cyclic α-glucan moiety that is reminiscent of cyclodextrin ingredients (*i.e.*, α-, β-, γ-cyclodextrin). The results of digestibility studies confirmed that the highly-branched cyclic dextrin molecules are digested in a manner consistent with the digestion of starch (amylopectin) and other starch-derived cyclic α-glucans (branched or non-branched). Specifically, the highly-branched cyclic dextrin molecules were shown by *in vitro* experimentation to be hydrolyzed by salivary and pancreatic α-amylases to maltose, maltotriose, and other small oligosaccharides, with subsequent digestion of these products to glucose by intestinal enzymes (Choi *et al.*, 2009). Ingestion of cyclic dextrin, highly branched by experimental animals and humans resulted in increased, postprandial glucose levels indicative of glucose absorption, thus further supporting that cyclic dextrin, highly branched is largely digested *in vivo* to glucose (Takii *et al.*, 1999, 2004). While small amounts of cyclic dextrin, highly branched may be incompletely digested, the undigested fraction of the carbohydrate products that escape hydrolysis would not be absorbed considering that the only absorbable product of dietary α-glucan digestion is glucose (*i.e.*, there is no mechanism in place for the absorption of oligo- or polysaccharides). Instead, the undigested fractions would pass into the large intestine for degradation by intestinal microflora, a normal and natural fermentation process (Stephen, 1991; Würsch, 1991; Brown, 1996; De Bie *et al.,* 1998; Topping and Clifton, 2001). Short-chain fatty acids are produced from the fermentation process, which are absorbed from the lower intestine and further metabolized to produce energy in well-characterized biochemical pathways. The results of the human study conducted by Takii *et al.* (2004), however, demonstrate that cyclic dextrin, highly branched is well tolerated in humans. The absence of any GI disturbances that are typically observed with non-digestible carbohydrates in this study demonstrates, therefore, that cyclic dextrin, highly branched is completely hydrolyzed and absorbed as glucose at bolus intakes of up to at least 35 g per person. In addition, although the dose applied in the human study does not cover the estimated heavy consumer daily intake of cyclic dextrin, highly branched by the total U.S. population (all-user 90th percentile intake of 48 g/person/day or 1,011 mg/kg body weight/day), intolerability to the ingredient is not

expected even at this level of intake considering that the daily intake of cyclic dextrin, highly branched is resultant of smaller intakes throughout the day and not due to a single large bolus intake [the maximum intended use level of the ingredient is 25 g per RACC (21 CFR 101.12 – U.S. FDA, 2009)]. Thus, cyclic dextrin, highly branched, undergoes normal carbohydrate digestion and would not be associated with intolerability issues at the estimated daily intake levels. Therefore, such consumption levels do not constitute a safety issue, particularly considering that the calculated estimated intake levels of the ingredient are highly conservative estimates.

The results of animal toxicity studies conducted on cyclic dextrin, highly branched and γ-cyclodextrin are supportive of the safety of cyclic dextrin, highly branched for human consumption at the intended levels of use. An oral LD_{50} of greater than 2,000 mg/kg body weight was established for cyclic dextrin, highly branched in Wistar rats. In addition, oral LD_{50} values of greater than 8,000 and 15,000 mg/kg body weight in Sprague-Dawley rats and ICR mice, respectively, were estimated for γ-cyclodextrin based on acute toxicity studies.

Although subchronic and chronic toxicity data on cyclic dextrin, highly branched were not available, 13-week and 1-year (in rats only) oral toxicity studies conducted with γ-cyclodextrin indicate that repeated administration of γ-cyclodextrin at dietary levels of up to 20% was well-tolerated and not associated with any compound-related adverse effects or death in Wistar rats (Lina and Bär, 1998; Lina, 1999) or Beagle dogs (Til and Bär, 1998). Although a slight reduction in body weight, soft stools, and enlargement of the full and empty cecum were consistently observed at the 20% level, these effects also were observed, and were more pronounced, upon administration of a diet consisting of 20% lactose, a carbohydrate that is incompletely digested in the small intestine of rats (Dahlqvist and Thomson, 1964). Other reported minor changes observed at the 20% level were transient and considered not toxicologically significant, but rather attributed to the presence of a large amount of an osmotically active substance in the large intestine. Thus, repeated exposure to orally administered γ-cyclodextrin *via* the diet produces physiological responses that are typically associated with the ingestion of high levels of incompletely digested carbohydrates, and therefore, are not of toxicological concern (Bär, 1985; Newberne *et al.*, 1988). Under the conditions of the 13-week subchronic studies, the NOAEL for γ-cyclodextrin was determined to be 20% in the diet, the highest level tested, equivalent to approximately 9 and 11 g/kg body weight/day for male and female Wistar rats, respectively (Lina, 1999). Under the conditions of the 1-year long-term study, the NOAEL for γ-cyclodextrin was determined to be 20% in the diet, the highest level tested, equivalent to approximately 9 and 11 g/kg body weight/day for male and female Wistar rats, respectively (Lina, 1999). Similar physiological effects, as observed with γ-cyclodextrin, may be expected with the cyclic dextrin, highly branched ingredient; however, as discussed above, cyclic dextrin, highly branched is likely completely digested in humans following consumption.

Cyclic dextrin, highly branched was shown to be non-mutagenic *in vitro* in the standard bacterial reverse mutation assay (Choi *et al.,* 2009). γ-Cyclodextrin also was non-mutagenic and non-genotoxic in both *in vitro* and *in vivo* validated systems (Blijleven, 1991; Immel, 1991; de Vogel and van Delft, 1996).

Developmental toxicity studies conducted in Wistar rats and New Zealand white rabbits demonstrated that administration of γ-cyclodextrin during gestation at dietary levels of up to 20% (approximately 11 g/kg body weight/day for rats and 5 to 7 g/kg body weight/day in rabbits) was not maternally toxic (Waalkens-Berendsen *et al.*, 1998a,b). Additionally, *in utero* exposure to γ-cyclodextrin at levels of up to 20% of the maternal diet did not result in embryotoxicity, fetotoxicity, or teratogenicity in rats or rabbits (Waalkens-Berendsen *et al.*, 1998a,b). Therefore, no adverse effects on development are expected to be associated with the large-ring cyclic α-glucan moiety of cyclic dextrin, highly branched.

The safety of cyclic dextrin, highly branched is further supported by the results of human studies conducted with the cyclic dextrin, highly branched ingredient at a dose relevant to the intended use levels of the ingredient. Results of a study conducted in healthy subjects to evaluate tolerability of cyclic dextrin, highly branched indicated that the frequency of GI discomforts, such as flatulence or belching, following consumption of a sports drink composed of 10% cyclic dextrin, highly branched (providing approximately 35 g of cyclic dextrin, highly branched per person) was comparable to that after consumption of water (Takii *et al.*, 2004). Likewise, randomized, double blind, cross-over trials conducted in healthy human volunteers demonstrated that consumption of single doses of up to 50 g of γ-cyclodextrin was well-tolerated and did not induce GI symptoms or discomfort in comparison to equal amounts of maltodextrin (Koutsou *et al.*, 1999; Asp *et al.*, 2006). Collectively, the human tolerability data available on cyclic dextrin, highly branched and γ-cyclodextrin indicate that cyclic dextrin, highly branched can be consumed in considerable amounts without adverse effects or tolerability issues. Additionally, the highly-branched cyclic molecules of cyclic dextrin, highly branched are rapidly hydrolyzed and not absorbed intact; therefore, the cyclic α-glucan moiety of cyclic dextrin, highly branched would not have any adverse effects on nutrient absorption and would not induce hemolytic effects. Furthermore, the data indicate that ingestion of cyclic dextrin, highly branched will not have any physiologically relevant effects on GET (Takii *et al.,* 2005). Thus, the results of the human study conducted with cyclic dextrin, highly branched support the maximum intended use level of the ingredient of 25 g per RACC (21 CFR 101.12 – U.S. FDA, 2009). Moreover, the ingredient does not pose any safety concerns given that modified food starches are prevalent constituents of the human diet with a long history of safe use in food and that the ingredient is efficiently digested to glucose, which is a safe product of carbohydrate digestion as described above. Thus, repeated consumption of cyclic dextrin, highly branched would not produce any adverse effects.

Together, the above data provided support the conclusion that the consumption of cyclic dextrin, highly branched under the intended conditions of use would not be expected to produce adverse effects in consumers.

Finally, the Expert Panel convened on behalf of Ezaki, independently and collectively, critically evaluated the data and information summarized above and concluded that the intended uses of cyclic dextrin, highly branched, trade named Cluster Dextrin® (CCD®), produced consistently with cGMP and meeting appropriate food grade specifications described herein, are safe and suitable. Furthermore, the Expert Panel unanimously concluded that the intended uses of cyclic dextrin, highly branched are GRAS based on scientific procedures. It is also Ezaki's opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, Ezaki has concluded that cyclic dextrin, highly branched is GRAS under the intended conditions of use on the basis of scientific procedures; therefore, the ingredient is excluded from the definition of a food additive and thus may be marketed and sold for the uses designated above in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

V. REFERENCES

Abdullah, M.; French, D.; Robyt, J.F. 1966. Multiple attack by α-amylases. Arch Biochem Biophys 114(3):595-598.

Asp, M.L.; Hertzler, S.R.; Chow, J.; Wolf, B.W. 2006. Gamma-cyclodextrin lowers postprandial glycemia and insulinemia without carbohydrate malabsorption in healthy adults. J Am Coll Nutr 25(1):49-55.

Bär, A. 1985. Safety assessment of polyol sweeteners: Some aspects of toxicity. Food Chem 16(3&4):231-241.

Bar, R.; Ulitzur, S. 1994. Bacterial toxicity of cyclodextrins: luminuous *Escherichia coli* as a model. Appl Microbiol Biotechnol 41(5):574-577.

Bárdos, L.; Gálné, F.M.; Szente, L. 1989. Absorption of vitamin A from β-cyclodextrin inclusion complex. Allattenyésztés Takarmányozás 38:263-268. Cited In: Munro *et al.,* 2004.

Bellringer, M.E.; Smith, T.G.; Read, R.; Gopinath, C.; Olivier, P. 1995. β-Cyclodextrin: 52-week toxicity studies in the rat and dog. Food Chem Toxicol 33(5):367-376.

Blijleven, W.G.H. 1991 [unpublished]. Examination of gamma-cyclodextrin for mutagenic activity in the Ames test. Report No. V91.027. Report from TNO-CIVO Institute; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd; Binningen, Switzerland. Cited In: JECFA, 1999.

Brown, I. 1996. Complex carbohydrates and resistant starch. Nutr Rev 54(11, Part 2):S115-S119.

Buléon, A.; Colonna, P.; Planchot, V.; Ball, S. 1998. Starch granules: structure and biosynthesis. Int J Biol Macromol 23(2):85-112.

Caballería, J. 2003. Current concepts in alcohol metabolism. Ann Hepatol 2(2): 60-68.

CDC. 2006. Analytical and Reporting Guidelines: The National Health and Nutrition Examination Survey (NHANES). Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS); Hyattsville, Maryland. Available from: http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/nhanes_analytic_guidelines_dec_2005.pdf.

Choi, S.S.; Danielewska-Nikiel, B.; Ohdan, K.; Kojima, I.; Takata, H.; Kuriki, T. 2009. Safety evaluation of highly-branched cyclic dextrin and a 1,4-α-glucan branching enzyme from *Bacillus stearothermophilus*. Regul Toxicol Pharmacol 55(3):281-290.

Cravotto, G.; Binello, A.; Baranelli, E.; Carraro, P.; Trotta, F. 2006. Cyclodextrins as food additives and in food processing. Curr Nutr Food Sci 2(4):343-350.

Dahlqvist, A.; Thomson, D.L. 1964. The digestion and absorption of lactose by the intact rat. Acta Physiol Scand 61:20-33.

De Bie, A.T.; Van Ommen, B.; Bär, A. 1998. Disposition of [(^{14})C]γ-cyclodextrin in germ-free and conventional rats. Regul Toxicol Pharmacol 27(2):150-158.

de Vogel, N.; van Delft, J.H.M. 1996 [unpublished]. Chromosome aberration test with gamma-cyclodextrin in cultured human lymphocytes. Report No. V96.398 from TNO-CIVO Institutes; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd.; Binningen, Switzerland. Cited In: JECFA, 1999.

Drozdowski, L.A.; Thomson, A.B. 2006. Intestinal sugar transport. World J Gastroenterol 12(11):1657-1670.

Gotsev, M.G.; Ivanov, P.M.; Jaime, C. 2007. Molecular dynamics study of the conformational dynamics and energetics of some large-ring cyclodextrins (CD*n*, *n* = 24, 25, 26, 27, 28, 29). Chirality 19(3):203-213.

Gray, G.M. 1992. Starch digestion and absorption in nonruminants. J Nutr 122(1):172-177.

Hirayama, F.; Yamamoto, M.; Uekama, K. 1992. Acid-catalyzed hydrolysis of maltosyl-β-cyclodextrin. J Pharm Sci 81(9):913-916.

Immel, H.R. 1991 [unpublished]. Examination of gamma-cyclodextrin in the micronucleus test. Report No. V90.436 from TNO-CIVO Institutes; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd.; Binningen, Switzerland. Cited In: JECFA, 1999.

Irie, T.; Otagiri, M.; Sunada, M.; Uekama, K.; Ohtani, Y.; Yamada, T.; Sugiyama, Y. 1982. Cyclodextrin-induced hemolysis and shape changes of human erythrocytes in vivo. J Pharmacobiodyn 5(9):741-744.

Ivanov, P.M.; Jaime, C. 2004. Insights into the structure of large-ring cyclodextrins through molecular dynamics simulations in solution. J Phys Chem B 108(20):6261-6274.

JECFA. 1999. γ-Cyclodextrin. In: Safety Evaluation of Certain Food Additives. 51st Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), June 9-18, 1998. World Health Organization (WHO); Geneva, Switz., WHO Food Additives Series, No. 42, pp. 183-202. Available from: http://www.inchem.org/documents/jecfa/jecmono/v042je11.htm.

Kondo, H.; Nakatani, H.; Hiromi, K. 1990. *In vitro* action of human and porcine α-amylases on cyclomalto-oligosaccharides. Carbohydr Res 204:207-213.

Koutsou, G.A.; Storey, D.M.; Bär, A. 1999. Gastrointestinal tolerance of γ-cyclodextrin in humans. Food Addit Contam 16(7):313-317.

Leroy-Lechat, F.; Wouessidjewe, D.; Andreux, J.-P.; Puisieux, F.; Duchêne, D. 1994. Evaluation of the cytotoxicity of cyclodextrins and hydroxypropylated derivatives. Int J Pharm 101(1&2):97-103.

Li, Z.; Wang, M.; Wang, F.; Gu, Z.; Du, G.; Wu, J.; Chen, J. 2007. γ-Cyclodextrin: a review on enzymatic production and applications. Appl Microbiol Biotechnol 77(2):245-255.

Lina, B.A.R. 1999 [unpublished]. Chronic (1-year) toxicity study with gamma-cyclodextrin in rats. Unpublished study from TNO Nutrition and Food Research Institute; The Netherlands. Submitted to WHO by Bioresearch Management and Consulting Ltd. Cited In: JECFA, 2000.

Lina, B.A.; Bär, A. 1998. Subchronic oral toxicity studies with γ-cyclodextrin in rats. Regul Toxicol Pharmacol 27(2):178-188.

Maestre, I.; Bea, I.; Ivanov, P.M.; Jaime, C. 2007. Structural dynamics of some large-ring cyclodextrins. A molecular dynamics study: an analysis of force field performance. Theor Chem Acc 117(1):85-97.

Marshall, J.J.; Miwa, I. 1981. Kinetic difference between hydrolyses of γ-cyclodextrin by human salivary and pancreatic α-amylases. Biochim Biophys Acta 661(1):142-147.

Matsuda, K.; Mera, Y.; Segawa, Y.; Uchida, I.; Yokomine, A.; Takagi, K. 1983. Acute toxicity study of γ-cyclodextrin (γ-CD) in mice and rats. Oyo Yakuri 26(2):287-291.

Munro, I.C.; Newberne, P.M.; Young, V.R.; Bär, A. 2004. Safety assessment of γ-cyclodextrin. Regul Toxicol Pharmacol 39(Suppl. 1):S3-S13.

Newberne, P.N.; Conner, M.W.; Estes, P. 1988. The influence of food additives and related materials on lower bowel structure and function. Toxicol Pathol 16(2):184-197.

Nishimura, T.; Kometani, T.; Nakae, T.; Takii, H.; Okada, S. 1996. Cyclic α-1,4-Glucan Formation by Bacterial α-Amylases. J Ferment Bioengineer 81(1):26-31.

Ohtani, Y.; Irie, T.; Uekama, K.; Fukunaga, K.; Pitha, J. 1989. Differential effects of α-, β- and γ-cyclodextrins on human erythrocytes. Eur J Biochem 186(1&2):17-22.

Okada, Y.; Kubota, Y.; Koizumi, K.; Hizukuri, S.; Ohfuji, T.; Ogata, K. 1988. Some properties and the inclusion behavior of branched cyclodextrins. Chem Pharm Bull (Tokyo) 36(6):2176-2185.

Seitz, H.K; Pöschl, G. 1997. The role of gastrointestinal factors in alcohol metabolism. Alcohol Alcohol 32(5): 543-549.

Stephen, A.M. 1991. Starch and dietary fibre: their physiological and epidemiological interrelationships. Can J Physiol Pharmacol 69(1):116-120.

Szejtli, J.; Gerlóczy, A.; Fónagy, A. 1983. Improvement of the absorption of ^{3}H-cholecalciferol by formation of its cyclodextrin complex. Pharmazie 38(2):100-101. Cited In: Munro *et al.,* 2004.

Takii, H.; Ishihara, K.; Kometani, T.; Okada, S.; Fushiki, T. 1999. Enhancement of swimming endurance in mice by highly branched cyclic dextrin. Biosci Biotechnol Biochem 63(12):2045-2052.

Takii, H.; Kometani, T.; Nishimura, T.; Kuriki, T.; Fushiki, T. 2004. A sports drink based on highly branched cyclic dextrins generates few gastrointestinal disorders in untrained men during bicycle exercise. Food Sci Technol Res 10(4):428-431.

Takii, H.; Takii (Nagao), Y.; Kometani, T.; Nishimura, T.; Nakae, T.; Kuriki, T.; Fushiki, T. 2005. Fluids containing a highly branched cyclic dextrin influence the gastric emptying rate. Int J Sports Med 26(4):314-319.

Til, H.P.; Bär, A. 1998. Subchronic (13-week) oral toxicity study of γ-cyclodextrin in dogs. Regul Toxicol Pharmacol 27(2):159-165.

Topping, D.L.; Clifton, P.M. 2001. Short-chain fatty acids and human colonic function: roles of resistant starch and nonstarch polysaccharides. Physiol Rev 81(3):1031-1064.

Toyoda, K.; Shoda, T.; Uneyama, C.; Takada, K.; Takahashi, M. 1997. Carcinogenicity study of β-cyclodextrin in F344 rats. Food Chem Toxicol 35(3&4):331-336.

U.S. FDA. 1997. Substances generally recognized as safe; Proposed rule [21 CFR Parts 170, 184, 186, and 570; Docket No. 97N-0103]. Fed Regist (US) 62(74):18937-18964.

U.S. FDA. 2000a. Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed: Polychlorinated Biphenyls (PCBs). U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN); Rockville, Maryland, Industry Activities Staff Booklet, Aug. 2000. Available from: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm#poly.

U.S. FDA. 2000b. Agency Response Letter GRAS Notice No. GRN 000046 [gamma Cyclodextrin]. U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Premarket Approval; College Park, Maryland. Available from: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=46 [Sep. 22, 2000].

U.S. FDA. 2001. Agency Response Letter GRAS Notice No. GRN 000074 [beta-Cyclodextrin]. U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety; College Park, Maryland. Available from: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=74 [Oct. 25, 2001].

U.S. FDA. 2004. Agency Response Letter GRAS Notice No. GRN 000155 [alpha-Cyclodextrin]. U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety; College Park, Maryland. Available from: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=155 [Dec. 22, 2004].

U.S. FDA. 2009. U.S. Code of Federal Regulations (CFR). Title 21—Food and Drugs (Food and Drug Administration). U.S. Government Printing Office (GPO); Washington, DC, pp. 5-9. Available from: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 [see Table for CFR Sections]

Table of CFR ections Referenced (Title 21—Food and Drugs)		
Part	**Section §**	**Section Title**
101—Food labeli	101.12	Reference amounts customarily consumed per eating occasion
170—Food addit s	170.3	Definitions
	170.30	Eligibility for classification as generally recognized as safe (GRAS)
172—Food addit s permitted for direct addition to food f uman consumption	172.340	Fish protein isolate
173—Secondary ect food additives permitted in food human consumption	173.25	Ion-exchange resins
	173.165	Candida lipolytica
178—Indirect fo dditives: Adjuvants, production aids. d sanitizers	178.3297	Colorants for polymers [Diatomaceous earth]
182—Substanc enerally recognized as safe	182.1057	Hydrochloric acid
184—Direct food ubstances affirmed as generally recogni d as safe	184.1148	Bacterially-derived carbohydrase enzyme preparation
	184.1293	Ethyl alcohol
	184.1763	Sodium hydroxide

USDA. 2000. 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals (CSFII) and Diet and Health Knowledge Survey (DHKS) (On CD-ROM). U.S. Department of Agriculture (USDA); Riverdale, Maryland [PB2000-500027].

USDA. 2009. What We Eat In America: National Health and Nutrition Examination Survey (NHANES): 2003-2004. U.S. Department of Agriculture (USDA); Riverdale, Maryland. Available from: http://www.ars.usda.gov/Services/docs.htm?docid=13793#release.

Waalkens-Berendsen, D.H.; Smits van Prooije, A.E.; Bär, A. 1998a. Embryotoxicity and teratogenicity study with γ-cyclodextrin in rabbits. Regul Toxicol Pharmacol 27(2):172-177.

Waalkens-Berendsen, D.H.; Verhagen, F.J.; Bär, A. 1998b. Embryotoxicity and teratogenicity study with γ-cyclodextrin in rats. Regul Toxicol Pharmacol 27(2):166-171.

Würsch, P. 1991. Metabolism and tolerance of sugarless sweeteners. In: Rugg-Gunn, A.J. (Ed.). Sugarless: The Way Forward. Elsevier Applied Science; New York, pp. 32-51.

Yoshida, A.; Arima, H.; Uekama, K.; Pitha, J. 1988. Pharmaceutical evaluation of hydroxyalkyl ethers of β-cyclodextrins. Int J Pharm 46(3):217-222.

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APPENDIX A

APPENDIX A

EXPERT PANEL CONSENSUS STATEMENT REGARDING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CYCLIC DEXTRIN, HIGHLY BRANCHED FOR USE IN FOODS

EXPERT PANEL CONSENSUS STATEMENT REGARDING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF CYCLIC DEXTRIN, HIGHLY BRANCHED FOR USE IN FOODS

July 15, 2008

INTRODUCTION

At the request of Ezaki Glico Co., Ltd. (Ezaki Glico), an Expert Panel (the "Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and information, and determine whether, under the conditions of intended use as a food ingredient, cyclic dextrin, highly branched (Cyclic Cluster Dextrin; CCD) would be Generally Recognized as Safe (GRAS) based on scientific procedures. The Panel consisted of the below-signed qualified scientific experts: Dr. Joseph F. Borzelleca (Virginia Commonwealth University School of Medicine), Dr. Paul M. Kuznesof (pmKuznesof, LLC), and Dr. William J. Waddell (University of Louisville School of Medicine). *Curricula vitae* evidencing the Panel members' qualifications for evaluating the safety of food ingredients are provided in Attachment 1.

The Panel, independently and collectively, critically examined a comprehensive package of scientific information and data compiled from the literature and other published sources through March of 2008 by Cantox Health Sciences International (Cantox). In addition, the Panel evaluated other information deemed appropriate or necessary, including data and information provided by Ezaki Glico. The information evaluated by the Panel included details pertaining to the method of manufacture and product specifications, supporting analytical data, intended use-levels in specified food products, consumption estimates for all intended uses, and a comprehensive assessment of the available scientific literature pertaining to the safety of CCD and structurally similar saccharides, including γ-cyclodextrin.

Following independent, critical evaluation of such data and information, the Panel convened on 15 July 2008 and unanimously concluded that the intended uses in traditional foods described herein for CCD, meeting appropriate food-grade specifications as described in the supporting dossier [Documentation Supporting the Evaluation of Cyclic Dextrin, Highly Branched As Generally Recognized As Safe (GRAS) For Use In Traditional Food Products] and manufactured consistent with current Good Manufacturing Practices (GMP), are GRAS based on scientific procedures. A summary of the basis for the Panel's conclusion is provided below.

SUMMARY AND BASIS FOR GRAS

Ezaki Glico intends to market CCD, a white, odorless powder primarily composed of highly-branched cyclic dextrin molecules for use in foods and beverages, including baked goods and baking mixes, beverages and beverage bases, breakfast cereals, coffee and tea, grain products and pastas, herbs, spices, seasonings, and flavorings, milk products, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, soft candy, and soups and soup mixes. Highly-branched cyclic dextrin molecules consist of α-(1,4)- and α-(1,6)-linked α-D-glucose units. The cyclic portion of the highly-branched dextrin molecules consists of approximately 16 to 100 α-(1,4)-linked glucose molecules. CCD is proposed for use in selected ready to eat foods and beverages at maximum use-levels of up to 30%. In products requiring further preparation prior to consumption (*i.e.*, beverage powders, powdered seasonings, and dry soup mixes) use-levels of up to 75% are proposed for CCD.

The consumption of CCD from all proposed food uses was estimated using the National Center for Health Statistics' (NCHS) 2003-2004 National Health and Nutrition Examination Surveys (NHANES) (CDC, 2006; USDA, 2008), which provide the most appropriate data for evaluating food-use and food-consumption patterns in the United States. Under the conditions of intended use of CCD in food, total U.S. population all users mean and 90th percentile daily intakes from all-proposed food-uses were estimated to be 22 g/person/day (425 mg/kg body weight/day) and 48 g/person/day (1,011 mg/kg body weight/day), respectively.

CCD is manufactured from the hydrolysis (liquefaction) of waxy corn starch using α-amylase from *B. subtilis*. *B. subtilis*- and *B. stearothermophilus*-derived α-amylase preparations are affirmed as GRAS by the FDA for use as direct food substances. The ring structure of CCD is subsequently formed *via* a cyclization reaction catalyzed by a non-genetically- or one of two genetically-modified bacterially-derived branching enzymes (BE and BE-01/BE-02, respectively). Native *B. stearothermophilus* is utilized to produce BE. BE-01 and BE-02 are produced by *B. subtilis* that has been genetically modified to express the gene encoding the branching enzyme from *B. stearothermophilus* or *Aquifex aelicus*, respectively. While an enzyme preparation (α-acetolactate decarboxylase) from a recombinant *B. subtilis* is permitted as a secondary direct food additive for use in food for human consumption by the FDA, recombinant *B. subtilis* with genes from *B. stearothermophilus* or *A. aeolicus* has not been previously approved for use in food by the FDA. Likewise, the non-genetically-modified branching enzyme produced by *B. stearothermophilus* (BE) also has not been approved for use in food by the FDA. Thus, assessment of the safety of CCD also included an evaluation of the safety of the branching enzymes that are involved in its production (BE, BE-01, and BE-02).

CCD is produced in accordance with current GMP and meets appropriate food-grade specifications. Lot samples are routinely assayed to verify compliance with specifications. Carry-over of the bacteria into the final product is prevented at the enzyme production stage, by lysing and removing the bacteria from the enzyme preparations. Thus, only a purified enzyme

filtrate is added to the starting material for the synthesis of CCD. Carry-over of active enzyme residues also is prevented by denaturing and inactivating the enzyme *via* pH reduction and high-temperature heating immediately following each enzyme-catalyzed reaction. In addition, downstream steps in the manufacturing process for CCD include purification to remove the biocatalysts and any residual particles. Final product specifications indicate that highly-branched cyclic dextrin molecules comprise at least 80% of the overall composition and that the final product possesses a dextrose equivalent of less than 5. Glucose is present in the final product at a level of less than 3.5%. Analysis of the final CCD product for microbes, heavy metals, pesticides, and mycotoxins indicate compliance with current FDA action and tolerance levels that have been set for these contaminants. All reagents and processing aids used in the manufacture of CCD are food-grade materials.

Studies evaluating the degradability, short-term toxicity, and mutagenicity of CCD, as well as tolerance in humans were used to substantiate the safety of CCD for human consumption. Since CCD largely consists of cyclic dextrin molecules that are structurally-related to γ-cyclodextrin (γ-cyclodextrin is a cyclic α-(1,4)-linked oligosaccharide that resembles the ring structure of the cyclic dextrin molecules in CCD), safety data on γ-cyclodextrin, including studies to assess metabolic disposition and subchronic and chronic toxicity, developmental and reproductive toxicity, mutagenicity and genotoxicity, and human tolerance studies were reviewed to support the degradability and safety of the cyclic moiety of the highly-branched cyclic dextrin molecules present in CCD.

CCD is synthesized from amylopectin, a component of starch, with further enzymatic modification to produce cyclic moieties. The branched linear polysaccharide portion of the dextrin molecules of CCD is structurally similar to amylopectin, whereas the ring structure is related to the naturally occurring cyclodextrin, γ-cyclodextrin. Accordingly, CCD is expected to share a similar digestive fate as that of starch (amylopectin) and γ-cyclodextrin. Amylopectin and γ-cyclodextrin are well known to be hydrolyzed by α-amylases and predominantly digested to glucose in the small intestine. *In vitro*, CCD also was confirmed to be hydrolyzed by human salivary α-amylase to maltose and maltotriose, natural products of starch digestion, with subsequent digestion of the di- and trisaccharides to glucose by intestinal enzymes as shown *in vitro* in the presence of rat intestinal homogenates (Unpublished Data, 2008). Ingestion of CCD by experimental animals and humans resulted in increased, postprandial glucose and/or insulin levels, thus further supporting that CCD is largely digested *in vivo* to glucose (Takii *et al.*, 1999, 2004). While small amounts of CCD may be incompletely digested, the undigested fraction of the carbohydrate products that escape hydrolysis would pass into the large intestine for degradation by intestinal microflora, a normal and natural fermentation process (Stephen, 1991). Short-chain fatty acids are produced from the fermentation process, which are absorbed from the lower intestine and further metabolized to produce energy in well-characterized biochemical pathways. Absence of any GI disturbances that are typically observed with non-

digestible carbohydrates in a human study conducted to assess CCD tolerability (Takii *et al.*, 2004) further confirms that CCD is largely hydrolyzed and absorbed as glucose.

The results of animal toxicity studies conducted on CCD and γ-cyclodextrin are supportive of the safety of CCD for human consumption at the intended levels of use. A single oral dose of 2,000 mg CCD/kg body weight did not result in acute toxicity or death in Wistar rats (An-Pyo Center, 1998a). Thus, an oral LD_{50} of greater than 2,000 mg/kg body weight was established for CCD in rats. Oral LD_{50} values of greater than 8,000 and 16,000 mg/kg body weight in Sprague-Dawley rats and ICR mice (Matsuda *et al.*, 1983; Immel, 1991), respectively, were estimated based on acute toxicity studies conducted with γ-cyclodextrin and provide further support for the low order of acute toxicity associated with CCD. Although subchronic toxicity data on CCD were not available, 13-week oral toxicity studies conducted with γ-cyclodextrin indicate that repeated administration of γ-cyclodextrin at dietary levels of up to 20% was well-tolerated and not associated with any compound-related adverse effects or death in Wistar rats (Lina and Bär, 1998) or Beagle dogs (Til and Bär, 1998). Although a slight reduction in body weight, soft stools, and enlargement of the full and empty cecum were consistently observed at the 20% level, these effects also were observed upon administration of a diet consisting of 20% lactose, a carbohydrate that is incompletely digested in the small intestine of rats (Dahlqvist and Thomson, 1964), but were more pronounced in the lactose group. Thus, subchronic exposure to orally administered γ-cyclodextrin *via* the diet produces physiological responses that are typically associated with the ingestion of high levels of incompletely digested carbohydrates (Bär, 1985; Newberne *et al.*, 1988). Under the conditions of these studies, the NOAEL for γ-cyclodextrin was determined to be 20% in the diet, the highest level tested, equivalent to approximately 11.4 and 12.7 g/kg body weight/day for male and female Wistar rats, respectively (Lina and Bär, 1998), and approximately 7.7 and 8.3 g/kg body weight/day for male and female Beagle dogs, respectively (Til and Bär, 1998).

Results similar to those observed in the short-term toxicity studies were observed following long-term exposure (1 year) of Wistar rats to γ-cyclodextrin. γ-Cyclodextrin at dietary levels of up to 20% was well-tolerated by rats and not associated with any compound-related adverse effects (Lina, 1999). A slight increase in cecum weight was observed in males at the 20% level as observed in the subchronic toxicity study, but was attributed to the presence of incompletely digested carbohydrates in the gut. Other reported minor changes observed at the 20% level were transient and considered not toxicologically significant, but rather attributed to the presence of a large amount of an osmotically active substance in the large intestine. Therefore, under the conditions of these studies, the NOAEL for γ-cyclodextrin was determined to be 20% in the diet, the highest level tested, equivalent to approximately 9 and 11 g/kg body weight/day for male and female Wistar rats, respectively (Lina, 1999).

Neither CCD nor γ-cyclodextrin exhibited any mutagenic or genotoxic potential *in vitro* in standard bacterial strains (Blijleven, 1991; An-Pyo Center, 1998b). Furthermore, γ-cyclodextrin

was shown to be non-clastogenic *in vitro* (Immel, 1991) and did not increase micronucleus frequency in mouse bone marrow cells *in vivo* (de Vogel and van Delft, 1996).

Reproductive toxicity studies conducted in Wistar rats and New Zealand white rabbits demonstrated that administration during gestation of γ-cyclodextrin at dietary levels of up to 20% (approximately 11 g/kg body weight/day for rats and 5 to 7 g/kg body weight/day in rabbits) did not affect reproductive performance or fertility (Waalkens-Berendsen *et al.*, 1998a,b). *In utero* exposure to γ-cyclodextrin at a maternal dietary level of 20% also did not result in embryotoxicity, fetotoxicity, or teratogenicity in rats or rabbits (Waalkens-Berendsen *et al.*, 1998a,b). Furthermore, γ-cyclodextrin at this level was not maternally toxic. Accordingly, human consumption of CCD at the intended use levels is not expected to be associated with any adverse reproductive or developmental effects attributable to the ring structure.

The highly-branched cyclic molecules of CCD are rapidly hydrolyzed and not absorbed intact; therefore the cyclic moieties of CCD would not have any adverse effects on nutrient absorption and would not induce hemolytic effects. Furthermore, ingestion of CCD will not have any physiologically relevant effects on gastric emptying time (GET).

Results of a study conducted in humans to evaluate tolerability of CCD indicated that the frequency of GI discomforts, such as flatulence or belching, following consumption of a sports drink composed of 10% CCD, providing approximately 35 g of CCD/person, was comparable to that after consumption of water (Takii *et al.*, 2004). Likewise, randomized, double blind, cross-over trials conducted in healthy human males and females demonstrated that consumption of single doses of up to 50 g of γ-cyclodextrin, a related cyclic dextrin, also was well-tolerated and did not induce GI symptoms or discomfort in comparison to equal amounts of maltodextrin (Koutsou *et al.*, 1999; Asp *et al.*, 2006). Symptoms assessed included belching, nausea, vomiting, bloating, borborygmia, abdominal cramping, abdominal distention, flatulence frequency, and stool frequency and consistency. Collectively, the human tolerability data available on CCD and γ-cyclodextrin indicate that human consumption of CCD at the intended use-levels is not expected to be associated with any adverse GI symptoms.

The intended CCD food-uses do not include products that would be marketed specifically for use by infants; however, some of the foods to which CCD is proposed for addition may be consumed by post-weaning infants and children. On a mg/kg body weight basis, infant (0 to 2 years) intakes of CCD were estimated to be up to 5 times higher compared to populations 3 years of age and older (3,062 mg/kg body weight/day *versus* 600 to 1,990 mg/kg body weight/day). Although information pertaining to the tolerability of CCD was identified only in adults, CCD is expected to be fully hydrolyzed to glucose following consumption and therefore is not anticipated to be associated with adverse gastrointestinal effects, including in post-weaning infants and children. Furthermore, based on the results of studies conducted with γ-cyclodextrin in mature rats, CCD is not expected to be absorbed systemically intact to any physiologically-meaningful degree following consumption in adults. Although the potential for

intact absorption of CCD was not specifically assessed in infants or young children, from a functional and histological perspective, the post-weaning infant and adult gastrointestinal tracts can be considered similar. Specifically, the absorption of intact macromolecules "does not appear to be any more significant in full-term neonates than in the adult" (Juskevich and Guyer, 1990). Furthermore, while it is well established that the gastric mucosa of newborns is permeable to macromolecules, the magnitude of this absorption is low and decreases substantially with increasing age, such that it is almost non-existent by weaning age (Axelsson *et al.*, 1989; Kuitunen *et al.*, 1994). Therefore, by the time post-weaning infants and young children reach the age where consumption of CCD-containing products would occur (*i.e.*, approximately 6 months to 1 year of age), differences in the absorption of macromolecules relative to adults are not expected. Accordingly, as in adults, CCD is not expected to be absorbed intact in infants or children.

Small amounts of CCD that may escape digestion to glucose in the upper gastrointestinal tract would be fermented in the lower gut of post-weaning infants and young children much like in adults. In humans, exposure to non-digestible carbohydrates that are fermented in the lower gut occurs from a very early stage. Human milk has been identified to contain over 100 different oligosaccharides at concentrations of up to 10 to 12 g/L that play a critical role in the development of the infant microflora (Stahl *et al.*, 1994; Kunz *et al.*, 1999; Veerman *et al.*, 2007). Additionally, given the prevalence of non-digestible carbohydrates in the diet, post-weaning infants and young children are exposed to significant amounts of such materials from food. The average intake of indigestible carbohydrates from various foods was estimated to be 1.9 g/day (ranging from 1.0 to 3.2 g/day) in infants ≤1 year of age and 3.7 g/day (ranging from 2.0 to 6.0 g/day) in children 1 to 5 years of age (Murphy *et al.*, 2008). Furthermore, intakes of indigestible carbohydrates in infants and young children did not differ significantly from those observed in populations aged 6 years of age and older (average 4.2 to 5.9 g/day; ranging from 2.1 to 9.8 g/day); however, on a mg/kg body weight basis, infants and young children are exposed to roughly 2.5-fold higher quantities of indigestible carbohydrates relative to adults (estimate based on a 10 kg child *versus* a 65 kg adult). Furthermore, in 2001, the Scientific Committee on Food (SCF) was asked to comment on the safety of the use of resistant short chain carbohydrates (oligofructose and oligogalactose) in infant products and concluded that use of such ingredients at concentrations of 0.8 g/dL was acceptable in follow-on formula intended for older infants (SCF, 2001). Accordingly, it is not expected that CCD, which will be predominantly hydrolyzed to glucose in the upper gastrointestinal tract, with only small quantities escaping digestion, would be associated with any significant gastrointestinal disturbances when consumed by infants or young children.

The bacterially-derived branching enzymes used in the production of CCD are not currently permitted for use in food in the U.S. Thus, the evaluation of CCD safety also included an assessment of the safety of the branching enzymes, as well as their sources. The production strains for the non-genetically modified BE (*B. stearothermophilus* TRBE14) and the genetically

modified BE-01 and BE-02 (*B. subtilis* strain 168) lack toxigenic potential, have a history of safe use in food processing, and have been determined to be derived from a safe lineage (de Boer and Diderichsen, 1991; U.S. EPA, 1997; Pedersen *et al.*, 2002; Olempska-Beer *et al.*, 2006). In the case of the genetically-modified enzymes, BE-01 and BE-02, the pUB110 vector carrying the gene encoding the branching enzyme from *B. stearothermophilus* or *Aquifex aelicus*, respectively, is a well characterized vector that has been determined to be safe for introducing new genetic material in *B. subtilis* for the purpose of producing enzymes used in the manufacture of food products (IFBC, 1990; Olempska-Beer *et al.*, 2006). All components used in the manufacture of BE, BE-01, and BE-02 are food-grade quality and following their production, the bacteria are lysed and removed from the enzyme preparations, prior to its addition to the CCD reaction mixture.

The safety of the isolated branching enzymes (BE, BE-01, and BE-02) has been evaluated in acute and subchronic toxicity studies, as well as *in vitro* mutagenicity assays. BE was not acutely toxic; the acute oral LD_{50} in Sprague-Dawley rats was greater than 2,000 mg/kg body weight (An-Pyo Center, 1999a). In the subchronic 13-week, oral toxicity studies, repeated oral administration of the branching enzymes BE-01 or BE-02 at doses of up to 15 mL/kg body weight/day (870 mg/kg body weight/day) to rats did not result in compound-related adverse effects (JBS Inc., 2004, 2006). Under the conditions of these studies, a NOAEL of 870 mg/kg body weight/day, the highest dose tested, was determined for both BE-01 and BE-02. Furthermore, BE was not mutagenic in a mouse lymphoma assay conducted in L5178Y $TK^{+/-}$ cells at concentrations of up to 5,000 µg/mL (An-Pyo Center, 1999b). BE-01 and BE-02 also were not mutagenic in the Ames assay conducted in *S. typhimurium* and *E. coli* or in the chromosomal aberration assay conducted in CHO cells at concentrations of up to 5,000 µg/plate (TNO, 2004a,b, 2006a,b). Based on the results of these studies, BE, BE-01, or BE-02 are not expected to be associated with any adverse effects. All enzymes are inactivated, denatured, and removed during the production of CCD.

The weight of the scientific evidence presented herein indicates that the intended uses of Ezaki Glico's CCD are safe and suitable. CCD is produced by Ezaki Glico in accordance with current GMP and meets appropriate food-grade specifications. CCD is composed only of α-D-glucose molecules and is derived from waxy corn starch, a major carbohydrate with a long history of human consumption. The ring moiety of the highly-branched dextrin molecules of CCD is structurally similar to the naturally occurring γ-cyclodextrin. Following consumption, CCD is digested to glucose and thus shares a similar digestive fate as starch and γ-cyclodextrin. The safety of the CCD product is confirmed and supported by a series of animal toxicity studies conducted on CCD and γ-cyclodextrin, as well as human studies assessing the tolerability of CCD and γ-cyclodextrin at dose levels relevant to the conditions of intended use of the CCD product in foods. Furthermore, the safety of the branching enzymes used in the synthesis of CCD is confirmed by a series of animal toxicity studies. The data and information summarized in this report demonstrate that the intended uses of Ezaki Glico's CCD, meeting appropriate

food-grade specifications as described in the supporting dossier and manufactured in accordance with current GMP, would be GRAS, based on the scientific procedures.

CONCLUSION

We, the Expert Panel, have, independently and collectively, critically evaluated the data and information summarized above and conclude that the intended uses of cyclic dextrin, highly branched (Cyclic Cluster Dextrin; CCD), meeting appropriate food-grade specifications presented in the supporting dossier [Documentation Supporting the Evaluation of Cyclic Dextrin, Highly Branched as Generally Recognized As Safe (GRAS) For Use In Traditional Food Products] and produced consistent with current good manufacturing practices (GMP), are safe and suitable.

We further conclude that the intended uses of cyclic dextrin, highly branched (Cyclic Cluster Dextrin; CCD) meeting appropriate food-grade specifications presented in the supporting dossier and produced consistent with current GMP are GRAS based on scientific procedures.

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

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15 July 2008
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REFERENCES

An-Pyo Center. 1998a [unpublished]. A single-dose oral toxicity study of cluster dextrin in rats. Prepared by: Biosafety Research Centre, Food, Drugs, and Pesticides (An-Pyo Center) for Ezaki Glico Co. Ltd. Study No. 4030 (261-001).

An-Pyo Center. 1998b [unpublished]. Bacterial reverse mutation test of cluster dextrin. Prepared by: Biosafety Research Centre, Food, Drugs, and Pesticides (An-Pyo Center) for Ezaki Glico Co. Ltd. Study No. 4032 (261-003).

An-Pyo Center. 1999a [unpublished]. A single-dose toxicity study of 6-α-glucanotransferase derived from *Bacillus stearothermophilus* TRBE14 strain in rats. Prepared by: Biosafety Research Centre, Food, Drugs, and Pesticides (An-Pyo Center) for Ezaki Glico Co. Ltd. Study No. 4326 (261-005).

An-Pyo Center. 1999b [unpublished]. Mouse lymphoma assay (MLA) of 6-α-glucanotransferase derived from *Bacillus stearothermophilus* TRBE14 strain. Prepared by: Biosafety Research Centre, Food, Drugs, and Pesticides (An-Pyo Center) for Ezaki Glico Co. Ltd. Study No. 4033 (261-004).

Asp, M.L.; Hertzler, S.R.; Chow, J.; Wolf, B.W. 2006. Gamma-cyclodextrin lowers postprandial glycemia and insulinemia without carbohydrate malabsorption in healthy adults. J Am Coll Nutr 25(1):49-55.

Bär, A. 1985. Safety assessment of polyol sweeteners: Some aspects of toxicity. Food Chem 16(3&4):231-241.

Blijleven, W.G.H. 1991 [unpublished]. Examination of gamma-cyclodextrin for mutagenic activity in the Ames test. Report No. V91.027. Report from TNO-CIVO Institute; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd; Binningen, Switzerland. Cited In: JECFA, 1999.

CDC. 2006. Analytical and Reporting Guidelines: The National Health and Nutrition Examination Survey (NHANES). Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS); Hyattsville, Maryland. Available from: http://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/nhanes_analytic_guidelines_dec_2005.pdf.

Dahlqvist, A.; Thomson, D.L. 1964. The digestion and absorption of lactose by the intact rat. Acta Physiol Scand 61:20-33.

de Boer, A.S.; Diderichsen, B. 1991. On the safety of *Bacillus subtilis* and *B. amyloliquefaciens*: a review. Appl Microbiol Biotechnol 36(1):1-4.

de Vogel, N.; van Delft, J.H.M. 1996 [unpublished]. Chromosome aberration test with gamma-cyclodextrin in cultured human lymphocytes. Report No. V96.398 from TNO-CIVO Institutes; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd.; Binningen, Switzerland. Cited In: JECFA, 1999.

IFBC. 1990. Chapter 4: Safety evaluation of foods and food ingredients derived from microorganisms. Regul Toxicol Pharmacol 12(3, Part 2):S114-S128.

Immel, H.R. 1991 [unpublished]. Examination of gamma-cyclodextrin in the micronucleus test. Report No. V90.436 from TNO-CIVO Institutes; Zeist, Netherlands. Submitted to WHO by Bioresco Ltd.; Binningen, Switzerland. Cited In: JECFA, 1999.

JBS Inc. 2004 [unpublished]. Thirteen-week oral toxicity study of BE-01 in rats. Prepared by: Gifu Research Laboratories, JBS Inc. for Ezaki Glico Co. Ltd. Study No. JBS-03-ROSA-642.

JBS Inc. 2006 [unpublished]. Thirteen-week oral toxicity study of BE-02 in rats. Prepared by: Gifu Research Laboratories, JBS Inc. for Ezaki Glico Co. Ltd. Study No. JBS-05-ROSA-206.

Koutsou, G.A.; Storey, D.M.; Bär, A. 1999. Gastrointestinal tolerance of γ-cyclodextrin in humans. Food Addit Contam 16(7):313-317.

Lina, B.A.R. 1999 [unpublished]. Chronic (1-year) toxicity study with gamma-cyclodextrin in rats. Unpublished study from TNO Nutrition and Food Research Institute; The Netherlands. Submitted to WHO by Bioresearch Management and Consulting Ltd. Cited In: JECFA, 2000.

Lina, B.A.; Bär, A. 1998. Subchronic oral toxicity studies with γ-cyclodextrin in rats. Regul Toxicol Pharmacol 27(2):178-188.

Matsuda, K.; Mera, Y.; Segawa, Y.; Uchida, I.; Yokomine, A.; Takagi, K. 1983. Acute toxicity study of γ-cyclodextrin (γ-CD) in mice and rats. Oyo Yakuri 26(2):287-291.

Newberne, P.N.; Conner, M.W.; Estes, P. 1988. The influence of food additives and related materials on lower bowel structure and function. Toxicol Pathol 16(2):184-197.

Olempska-Beer, Z.S.; Merker, R.I.; Ditto, M.D.; DiNovi, M.J. 2006. Food-processing enzymes from recombinant microorganisms—a review. Regul Toxicol Pharmacol 45(2):144-158.

Pedersen, P.B.; Bjornvad, M.E.; Rasmussen, M.D.; Petersen, J.N. 2002. Cytotoxic potential of industrial strains of *Bacillus* sp. Regul Toxicol Pharmacol 36(2):155-161.

Stephen, A.M. 1991. Starch and dietary fibre: their physiological and epidemiological interrelationships. Can J Physiol Pharmacol 69(1):116-120.

Takii, H.; Ishihara, K.; Kometani, T.; Okada, S.; Fushiki, T. 1999. Enhancement of swimming endurance in mice by highly branched cyclic dextrin. Biosci Biotechnol Biochem 63(12):2045-2052.

Takii, H.; Kometani, T.; Nishimura, T.; Kuriki, T.; Fushiki, T. 2004. A sports drink based on highly branched cyclic dextrins generates few gastrointestinal disorders in untrained men during bicycle exercise. Food Sci Technol Res 10(4):428-431.

Til, H.P.; Bär, A. 1998. Subchronic (13-week) oral toxicity study of γ-cyclodextrin in dogs. Regul Toxicol Pharmacol 27(2):159-165.

TNO. 2004a [unpublished]. Bacterial reverse mutation test with BE-01. Prepared by TNO Nutrition and Food Research for Ezaki Glico Co Ltd. TNO Report V 5005/15.

TNO. 2004b [unpublished]. Chromosomal aberration test with BE-01 in cultured Chinese Hamster Ovary (CHO) cells. Prepared by TNO Nutrition and Food Research for Ezaki Glico Co Ltd. TNO Report V 5002/11.

TNO. 2006a [unpublished]. Bacterial reverse mutation test with BE-02. Prepared by TNO Nutrition and Food Research for Ezaki Glico Co Ltd. TNO Report V 6805/01.

TNO. 2006b [unpublished]. Chromosomal aberration test with BE-02 in cultured Chinese Hamster Ovary (CHO) cells. Prepared by TNO Quality of Life for Ezaki Glico Co., Ltd. TNO Report V 6802/02 [Final].

U.S. EPA. 1997. Attachment I—Final Risk Assessment of *Bacillus Subtilis*. U.S. Environmental Protection Agency (U.S. EPA), Biotechnology Program under Toxic Substances Control Act (TSCA); Washington, DC. Available from: http://www.epa.gov/biotech_rule/pubs/pdf/fra009.pdf [February 1997].

Unpublished Data. 2008. [In vitro digestion test of CCD].

USDA. 2008. What We Eat In America: National Health and Nutrition Examination Survey (NHANES): 2003-2004. U.S. Department of Agriculture (USDA); Riverdale, Maryland. Available from: http://www.ars.usda.gov/Services/docs.htm?docid=13793#release.

Waalkens-Berendsen, D.H.; Smits van Prooije, A.E.; Bär, A. 1998a. Embryotoxicity and teratogenicity study with γ-cyclodextrin in rabbits. Regul Toxicol Pharmacol 27(2):172-177.

Waalkens-Berendsen, D.H.; Verhagen, F.J.; Bär, A. 1998b. Embryotoxicity and teratogenicity study with γ-cyclodextrin in rats. Regul Toxicol Pharmacol 27(2):166-171.

APPENDIX B

APPENDIX B

METHODS OF ANALYSIS

Analytical Methods

1) CCD Content

HPLC-MALLS-RI

Column:	Shodex OHpak SB806M HQ (8 × 300 mm) with a precolumn (OHpak SB-G)
Eluate:	0.1M $NaNO_3$
Flow:	1 mL/min
Temperature:	40 degree C
Detector:	Multi-angle laser light scattering photometer (Wyatt Technology, CA, USA) and a differential refractive index detector

Reference

H. Takata, et al. Properties of branching enzyme from hyperthermophilic bacterium, Aquifex aeolicus, and its potential for production of highly-branched cyclic dextrin. J. Appl. Glycosci. 50, 15-20, (2003).

Procedures

1. Dissolve sample to the eluent (0.5 % (w/w)), and filtrate through a 0.45 micrometer membrane.
2. Inject 50~80 microliter of the sample to the HPLC system
3. Data collection and calculation is carried out by using a Software ASTRA (Wyatt Technology) to obtain a cumulative curve of molecular weight
4. Calculate weight fraction of molecular weight 30,000~1,000,000 as CCD.

No. 10033078-Appendix

Analysis Method for Sulfur Dioxide

Sample name: Cluster Dextrin Lot. 09.2.11

<Distillation>

Receiving flask
|
Add 9 ml of 0.1 mol/l sodium hydroxide solution

Sampling flask
| + 1 ml of 1 % sodium azide solution
| + 2 ml of ethanol
| + 1 ml of 5 % dimedone solution
| + 1-2 drops of silicone resin
| + 10 ml of 25 % phosphoric acid
| + 10-15 ml of water
Set the sampling flask to a distillation apparatus
|
Aerate with nitrogen (5 minutes)
| + 2 g of sample
Set the sampling flask to the apparatus immediately
|
Heat the sampling flask with nitrogen aeration (Microburner, 10 minutes)
|
Remove the receiving flask
| Fill up to 15 ml with 0.1 mol/l sodium hydroxide solution
Sample solution

<Absorptiometry>

5 ml of the sample solution
| + 0.1 ml of water
| + 1 ml of reaction solution*
Stand for 15 minutes
|
Test solution A

5 ml of the sample solution
| + 0.1 ml of 0.3 % hydrogen peroxide
| + 1 ml of reaction solution*
Stand for 15 minutes
|
Test solution B

Measure the absorbance at 580 nm, and subtract the value of the test solution B from that of the test solution A.

* Reaction solution
Dissolve 0.08 g of pararosaniline hydrochloride in 40 ml of hydrochloric acid, and dilute to 200 ml with water. Dissolve 2 ml of 37 % formaldehyde solution with water, and dilute to 350 ml. Mix these two solutions together in equal volumes, and filter through membrane filter (0.45 μm) under reduced pressure.

No. 10033078-Appendix

Analysis Method for Protein [Kjeldahl Method]

Sample name: Cluster Dextrin Lot. 09.2.11

<Determination>

Weigh the sample (about 2 g) into a Kjeldahl digestion tube

+ Add about 15 ml of conc. H_2SO_4
+ Add about 5 g of catalyst ($CuSO_4$:K_2SO_4=1:9)
+ Add about 5 ml of hydrogen peroxide solution

Boil briskly until the solution becomes clear, and keep heating at least one hour with Foss Tecator Digester Lift System

Cool

+ Add about 80 ml of water

Distill, and titrate with Kjeltec Auto 2400 Analyzer

<Titration>

Titrate with 0.05 mol/l H_2SO_4 standard solution (V ml)
(Indicator: Bromcresol Green-Methyl red solution)

Obtain the blank value (B ml) for correction

<Calculation>

Protein (g/100g) = (V−B) × F × 0.0014 × K × 100／S

V: 0.05 mol/l H_2SO_4 solution (ml)
B: Blank (ml)
F: Titer of 0.05 mol/l H_2SO_4 standard solution
0.0014: Amount of nitrogen (g) equivalent to 1 ml of 0.05 mol/l H_2SO_4 standard solution
K: Nitrogen-to-protein conversion factor
S: Weight of the sample (g)

Analysis Method for Fat [Acid Hydrolysis Method]

Sample name: Cluster Dextrin Lot. 09.2.11

Weigh the sample (About 2—3 g) into a 50-ml beaker
|
Add about 2 ml of ethanol, and stir to prevent lumping
|
Add 10 ml of HCl, and mix well
|
Heat the beaker on a water bath for 40 minutes
|
Cool, and transfer the mixture to a Mojonnier fat-extraction tube with 10 ml of ethanol
|
Add 25 ml of diethyl ether, and stopper the tube, and shake vigorously for 30 seconds
|
Add 25 ml of petroleum ether, and stopper the tube, and shake vigorously for 30 seconds, and allow to stand until the upper layer becomes practically clear
|
Decant the ether layer (the upper layer) into a separatory funnel, and wash the lip of the tube with diethyl ether
|
Add 40 ml of mixture (diethyl ether:petroleum ether, 1:1) to the remaining liquid in the tube, and shake well, and allow to stand, and decant the ether layer into the separatory funnel
|
Add 30 ml of mixture (diethyl ether:petroleum ether, 1:1) to the remaining liquid in the tube, and shake well, and allow to stand, and decant the ether layer into the separatory funnel
|
Wash the ether later in the separatory funnel with H_2O until the washings are free from acid
|
Transfer the obtained ether-fat solution through a filter paper with Na_2SO_4 (anhydrous) to a Soxhlet flask that is weighed in advance (W_1)
|
Evaporate
|
Dry the Soxhlet flask in an air oven at 105 ℃ for 1 hour
|
Cool in a desiccator, and weigh (W_2)

<Calculation>

$$\text{Fat (g/100 g)} = \frac{W_2 - W_1}{S} \times 100$$

W_1: Constant weight of Soxhlet flask (g)
W_2: Weight of Soxhlet flask after evaporation (g)
S: Weight of the sample (g)

APPENDIX C

APPENDIX C

SUMMARY OF ANALYTICAL DATA

Summary of Analytical Data

Three (3) non-consecutive sample lots of the cyclic dextrin, highly branched ingredient manufactured with the use of the branching enzyme derived from non-genetically modified *B. stearothermophilus* TRBE14 (referred to as BE) (Lot Nos. 17.05.09, 18.06.01, and 18.02.08) were analyzed to verify that the manufacturing process produces a consistent product. Additionally, sample lots of the ingredient manufactured with the use of the branching enzyme derived from two genetically-modified *B. subtilis* 168 sources, referred to as BE-01 (Lot No. 07.11.14) and BE-02 (Lot No. 20.1.11), were analyzed to demonstrate that the product specifications also are met when enzymes from the genetically modified organism are used to perform the cyclization reaction. A summary of the physical, chemical, and microbiological product analyses for the 5 non-consecutive lots of cyclic dextrin, highly branched is presented in Table C-1. Heavy metal analyses were conducted in 3 additional non-consecutive lots of the ingredient, manufactured with BE, and are presented in Table C-2. The analytical data show conformity to the product specifications and the absence of any chemical impurities or microbial contamination. The product specifications and certificates of analysis are included in Attachment C-1 and C-2, respectively.

Table C-1 Analysis of Manufactured Lots of Cyclic Dextrin, Highly Branched

Specification Parameter	Specification Requirement	Manufacturing Lot Numbers				
		17.05.09[a]	18.06.01[b]	18.02.08[c]	07.11.14[d]	20.1.11[e]
Appearance	White powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor	Odorless	Conforms	Conforms	Conforms	Conforms	Conforms
Foreign matter	None	Conforms	Conforms	Conforms	Conforms	Conforms
Dextrose equivalents	<5	2.0	3.3	2.0	0.1	0.3
Assay (HBCD content) (%)	≥80	88.4 (92.5)[f]	83.9 (87.9)	89.7 (93.8)	96.5 (99.1)	92.5 (97.6)
Glucose (%)	<3.5	1.1 (1.2)	1.4 (1.5)	0.7 (0.7)	ND[g]	ND[g]
Saccharides < 30,000 MW (excluding glucose) and > 1,000,000 MW (excluding glucose) (%)	<14	6.0 (6.3)	10.1 (10.6)	5.2 (5.5)	0.9 (0.9)	2.3 (2.4)
Loss on drying (%)	<5.5	4.4	4.5	4.4	2.6	5.2
Residue on ignition (%)	<0.5	0.002	0.003	0.002	0.002	0.002
Microbiological Parameters						
Standard plate count (CFU/g)	<300	<300	<300	<300	<300	<300
Coliform count	Negative	Negative	Negative	Negative	Negative	Negative
Yeasts (CFU/g)	<50	<50	<50	<50	<50	<50
Molds (CFU/g)	<50	<50	<50	<50	<50	<50

As_2O_3 = Arsenic oxide; CFU = Colony-forming units; HBCD = highly-branched cyclic dextrin; ND = None detected.
[a] Production date: 2005/05/09

[b] Production date: 2006/06/01
[c] Production date: 2006/02/08
[d] Production date: 2007/11/14
[e] Production date: 2008/01/11
[f] Values in parentheses are expressed as the percent (%) of total carbohydrate content
[g] Less than 0.2%

Table C-2 Heavy Metal Analysis of Manufactured Lots of Cyclic Dextrin, Highly Branched

Specification Parameter	Specification Requirement	Limit of Detection	Production Year			Manufacturing Lot No.		
			2004	2005	2006	17.05.09	16.09.10	16.04.01
Heavy metals (ppm)	Less than 4	1	<1	<1	<1	N/A	N/A	N/A
Arsenic (As_2O_3) (ppm)	Less than 1	0.1	<0.1	<0.1	<0.1	N/A	N/A	N/A
Lead (ppm)	Lees than 1	0.05	N/A	N/A	N/A	<0.05	<0.05	<0.05

N/A = Not applicable.

The final ingredient also was analyzed for potential levels of protein and lipid due to residual enzyme and bacterial remnants, as well as for sulfur dioxide used in the production of starch from corn, in 3 non-consecutive lots. The analytical results are presented in Table C-3 and indicate that protein, lipid, and sulfur were not detected in 3 non-consecutive lots of cyclic dextrin, highly branched, thus demonstrating successful removal of the production enzymes and bacterial remnants during the filtration process and the absence of sulfur in the final ingredient. The certificates of analysis are provided in Attachment C-2.

Table C-3 Protein, Lipid, and Sulfur Dioxide Analysis of Manufactured Lots of Cyclic Dextrin, Highly Branched

Specification Parameter	Limit of Detection	Manufacturing Lot Numbers		
		17.05.09	16.09.10	16.04.01
Protein	0.1 g/100 g	<0.1	<0.1	<0.1
Lipid	0.1 g/100 g	<0.1	<0.1	<0.1
Sulfur dioxide	0.003 g/kg	<0.1	<0.1	<0.1

For a typical lot of corn imported from the U.S. to Japan, pesticide screening, comprising over 400 substances, is conducted for the Japanese Starch & Sweeteners Industry Association on an annual basis. The substance list is based on the list published by the Japanese Ministry of Health, Labour and Welfare. Results of analysis indicate that the levels of these substances in corn are below the limits of detection. The certificate of analysis is provided in Attachment C-2. Additionally, the Japanese Starch & Sweeteners Industry Association lists 69 substances as major chemicals used in the U.S. and also requires that testing is conducted for levels of these

substances once a year. The list provided by the Japanese Starch & Sweeteners Industry Association is based on the U.S. usage status of chemicals appearing in the U.S. Department of Agriculture (USDA) Agricultural Chemical Usage Field Crops Summaries for the years 2000 through 2008. Again, analytical results indicate that the levels of these substances in corn are below the limits of detection. The certificate of analysis is provided in Attachment C-2.

The association additionally lists 8 major pesticides/herbicides that should be monitored on a regular basis, which include aluminum phosphide, malathion, pirimiphos-methyl, atrazine, acetochlor, fenitrothion, glufosinate, and glyphosate. Ezaki monitors the levels of these 8 chemicals for every lot of corn. Analytical results for three non-consecutive lots of corn are summarized in Table C-4. The analysis confirmed the absence of these pesticide residues in the corn starting material. The certificates of analysis are provided in Attachment C-2.

Table C-4 Chemical Analysis of a Sample Lot of Corn

Substance	Certificate Number		
	US/39278.34641/07[a]	US/43337.46876[a]	989256.A594902506
Aluminum phosphide	Negative	Negative	Less than 0.05 ppm
Malathion	Negative	Negative	Less than 0.1 ppm
Pirimiphos-methyl	Negative	Negative	Less than 0.1 ppm
Atrazine	Negative	Negative	Less than 0.1 ppm
Acetochlor	Negative	Negative	Less than 0.1 ppm
Fenitrothion	Negative	Negative	Less than 0.1 ppm
Glufonsinate	Negative	Negative	Less than 0.1 ppm
Glyphosate	Negative	Negative	Less than 0.1 ppm

[a] The limit of detection for all substances was 1.0 ppm, except for malathion for which the limit of detection was 2.0 ppm.

Since mycotoxins are known contaminants of corn, the waxy corn starch used in the manufacture of cyclic dextrin, highly branched also was analyzed for mycotoxin content (aflatoxin and fumonisin). FDA has established an action level of 20 ppm for aflatoxin in food (U.S. FDA, 2000a). The analytical results are summarized in Table C-5 and showed no detectable levels of aflatoxin B_1 and B_2 or fumonisin B_1 and B_2 in three non-consecutive lots of the waxy corn starch. Certificates of analysis are provided in Attachment C-2.

Table C-5 Mycotoxin Analysis of Sample Lots of Waxy Corn Starch

Substance	Limit of Detection	Manufacturing Lot Numbers		
		050111	090118	100203
Aflatoxin B_1	1.0 ppb	Negative	Negative	Negative
Aflatoxin B_2	1.0 ppb	Negative	Negative	Negative
Fumonisin B_1	0.5 ppm	Negative	Negative	Negative
Fumonisin B_2	0.5 ppm	Negative	Negative	Negative

APPENDIX C
ATTACHMENT C-1
PRODUCT SPECIFICATIONS

2007/2/22
EZAKI GLICO CO.,LTD.

*1) Items for quality control of Cluster Dextrin

No	Items	Criterion	Method
1	Appearance	White powder	
2	Odor	Odorless	
3	Foreign object	Negative	
4	Moisture	<5.5%	
5	Ash	<0.05%	
6	Dextrose equivalent	<5	Modified Somogyii-Nelson
7	Content of Cluster Dextrin	> 85%	HPLC
8	Glucose	< 3.5%	Glucose-oxidase/peroxidase
9	Micro-organisms	<300/g	
10	Coliforms	Negative	
11	Moulds	<50/g	
12	Yeast	<50/g	
13	Heavy metals(as Pb)	<4μg/g	Colorimetric Analysis
14	Arsenic(as As_2O_3)	<1μg/g	Atomic Absorption Spectrometry

00000279

APPENDIX C
ATTACHMENT C-2
CERTIFICATES OF ANALYSIS AND OTHER ANALYTICAL DATA

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 17.05.09

Production Date : 2005/05/09

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White Powder	White Powder
Odor	Odorless	Odorless
Foreign object	Negative	Negative
Moisture	<5.5%	4.4%
Ash	<0.05%	0.002%
D E (Dextrose equivalent)	< 5	2.0
Content of Cluster Dextrin	>85%	92.5%
Glucose	<3.5%	1.2%
Micro-organisms	<300/g	0
Coliforms	Negative	Negative
Moulds	<50/g	0
Yeast	<50/g	0

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 18.06.01

Production Date : 2006/06/01

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White Powder	White Powder
Odor	Odorless	Odorless
Foreign object	Negative	Negative
Moisture	<5.5%	4.5%
Ash	<0.05%	0.003%
D E (Dextrose equivalent)	< 5	3.3
Content of Cluster Dextrin	>85%	87.9%
Glucose	<3.5%	1.5%
Micro-organisms	<300/g	0
Coliforms	Negative	Negative
Moulds	<50/g	0
Yeast	<50/g	0

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 18.02.08

Production Date : 2006/02/08

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White Powder	White Powder
Odor	Odorless	Odorless
Foreign object	Negative	Negative
Moisture	<5.5%	4.4%
Ash	<0.05%	0.002%
D E (Dextrose equivalent)	< 5	2.0
Content of Cluster Dextrin	>85%	93.8%
Glucose	<3.5%	0.7%
Micro-organisms	<300/g	0
Coliforms	Negative	Negative
Moulds	<50/g	0
Yeast	<50/g	0

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 07.11.14

Production Date : 2007/11/14

Branching enzyme used for production: BE-01

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White Powder	White Powder
Odor	Odorless	Odorless
Foreign object	Negative	Negative
Moisture	<5.5%	2.6%
Ash	<0.05%	0.002%
D E (Dextrose equivalent)	< 5	0.1
Content of Cluster Dextrin	>80%	99.1%
Glucose	<3.5%	Not Detected (<0.2%)
Micro-organisms	<300/g	0
Coliforms	Negative	Negative
Moulds	<50/g	0
Yeast	<50/g	0
Protein	-	Not Detected (<0.1%)
Lead	<1 ppm	0.06ppm

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 20.1.11

Production Date : 2008/01/11

ITEMS	SPECIFICATIONS	RESULTS
Appearance	White Powder	White Powder
Odor	Odorless	Odorless
Foreign object	Negative	Negative
Moisture	<5.5%	5.2%
Ash	<0.05%	0.002%
D E (Dextrose equivalent)	< 5	0.3
Content of Cluster Dextrin	>80%	97.6%
Glucose	<3.5%	Not Detected (<0.2%)
Micro-organisms	<300/g	0
Coliforms	Negative	Negative
Moulds	<50/g	0
Yeast	<50/g	0
Protein	-	Not Detected (<0.1%)
Lead	<1 ppm	Not Detected (<0.05ppm)

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : -

Production year : 2004

ITEMS	SPECIFICATIONS	RESULTS	DETECTION LIMIT
Heavy metals(as Pb)	<4 μg/g	Not detected	1 μg/g
Arsenic(as As_2O_3)	<1 μg/g	Not detected	0.1 μg/g

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : -

Production year : 2005

ITEMS	SPECIFICATIONS	RESULTS	DETECTION LIMIT
Heavy metals(as Pb)	<4 μg/g	Not detected	1 μg/g
Arsenic(as As_2O_3)	<1 μg/g	Not detected	0.1 μg/g

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : -

Production year : 2006

ITEMS	SPECIFICATIONS	RESULTS	DETECTION LIMIT
Heavy metals(as Pb)	<4 μg/g	Not detected	1 μg/g
Arsenic(as As_2O_3)	<1 μg/g	Not detected	0.1 μg/g

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 17.05.09

Production Date : 2005/05/09

ITEMS	RESULTS	Limit of detection	Method
Protein	<0.1 g/100g		Kjeldahl method
Lipid	<0.1 g/100g		Acid degradation method
sulfur dioxide	Not detectable	0.003 g/kg	Analytical method for food additive (2000) Sulfur dioxide (Method B)
Lead	Not detectable	0.05 ppm	Atomic absorption spectrophotometry

Report of Analysis

Product Name : Cluster Dextrin
Lot No. : 16.09.10
Production Date : 2004/09/10

ITEMS	RESULTS	Limit of detection	Method
Protein	<0.1 g/100g		Kjeldahl method
Lipid	<0.1 g/100g		Acid degradation method
sulfur dioxide	Not detectable	0.003 g/kg	Analytical method for food additive (2000) Sulfur dioxide (Method B)
Lead	Not detectable	0.05 ppm	Atomic absorption spectrophotometry

Report of Analysis

Product Name : Cluster Dextrin

Lot No. : 16.04.01

Production Date : 2004/04/01

ITEMS	RESULTS	Limit of detection	Method
Protein	<0.1 g/100g		Kjeldahl method
Lipid	<0.1 g/100g		Acid degradation method
sulfur dioxide	Not detectable	0.003 g/kg	Analytical method for food additive (2000) Sulfur dioxide (Method B)
Lead	Not detectable	0.05 ppm	Atomic absorption spectrophotometry

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Registered ISO 9001 : 2000 Laboratory

ORIGINAL

DATE: August 15, 2007.
No. JF54Z00222-2B

CERTIFICATE OF ANALYSIS (分析証明書)

APPLICANT(申請者):	Japan Starch & Sweetners Industry Association/Japan Corn Grits Association (日本スターチ・糖化工業会/社団法人 日本コーングリッツ協会)
SAMPLE DESCRIPTION(サンプル):	US Maize 2006 Crop (平成18年産アメリカ産トウモロコシ)
SAMPLE SUBMITTED(サンプル提供者):	MITSUI & CO., LTD. (三井物産株式会社)
PLACE OF SAMPLING (サンプル採取場所):	MINNESOTA WINNONA RIVER TERMINAL
SAMPLED BY(サンプル採取者):	MARK, SACKMASTER
DATE OF SAMPLING (サンプル採取日):	July 23, 2007. (平成19年7月23日)
CONDITION OF SAMPLE(サンプルの状態):	Cloth Bag (布製バッグ入り)
SAMPLE DATE RECEIVED(受領日):	August 2, 2007. (平成19年8月2日)

****

THIS IS TO CERTIFY that we, OMIC USA Inc., Portland, Oregon did carry out agricultural chemical residue analysis on the submitted sample with the above-mentioned details.
(OMIC USA Inc. で実施した上述の提出サンプルの分析について次のとおり証明する)

PLACE AND DATE OF ANALYSIS (分析所及び分析日)

At the laboratory of OMIC USA Inc., Portland, Oregon between August 2 and August 15, 2007
(分析場所：アメリカ合衆国オレゴン州ポートランド市在 OMIC USA Inc. 分析期間：平成19年8月2日～8月15日)
OMIC USA Inc.は日本厚生労働省の輸出国公的検査機関リストに指定検査機関(Registered laboratory)として登録されております。
(http://www.mhlw.go.jp/topics/yunyu/5/index.html をご参照ください。)

RESULTS (分析結果)

The contents of the required agricultural chemical residues and components are not detected and found as per the attached ANALYSIS RESULTS. (依頼を受けた農薬の検出結果は別紙のとおり)

This certificate refers to our intervention and findings at the time and place mentioned above only.

OMIC USA Inc.

President

Checked by

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分析結果一覧表(厚生労働省 平成19年度残留農薬モニタリング404項目)

NO.	Test Name(分析項目)		Japan 食品用基準	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	検体	米
1	1,1-ジクロロ-2,2-ビス(4-エチルフェニル)エタン	1,1-DICHLORO-2,2-BIS (4-ETHYLPHENYL)ETHANE	0.01	ND	0.03	GC-ECD	15	米
2	2, 2-DPA	2,2-DPA	0.1	ND	0.1	GC-ECD	15	米
3	2,4,5-T	2,4,5-T	ND(0.05)	ND	0.03	LC-MSMS	4-5	ナッ
4	2,4-D	2,4-D	0.05	ND	0.02	LC-MSMS	10	茶
5	2, 4-DB	2,4-DB	0.02	ND	0.02	LC-MSMS	15	米
6	4-クロルフェノキシ酢酸	4-CPA	0.02	ND	0.01	LC-MSMS	15	緑
7	BHC	BHC	0.2	ND	0.01	GC-ECD	9	虫
8	DCIP	DCIP	—(*0.01)	ND	0.02	GC-MSD	15	虫
9	DDT	DDT	0.2	ND	0.01	GC-ECD	9	虫
10	EPN	EPN	—(*0.01)	ND	0.01	GC-FPD	15	虫
11	EPTC	EPTC	0.1	ND	0.01	GC-MSD	9	茶
12	MCPA	MCPA	0.1	ND	0.03	LC-MSMS	9	ユ・調
13	MCPB	MCPB	0.02	ND	0.02	LC-MSMS	15	豆
14	TCMTB	TCMTB	0.1	ND	0.02	GC-ECD	15	麦
15	XMC	XMC	0.2	ND	0.01	LC-MSD	15	豆
16	γ-BHC	gamma-BHC (LINDANE)	0.3	ND	0.01	GC-ECD	15	虫
17	アイオキシニル	IOXYNIL	0.1	ND	0.05	LC-MSMS	15	豆
18	アゴリナトリン	AGRINATHRIN	0.1	ND	0.01	GC-MSD	9	虫
19	アザメチホス	AZAMETHIPHOS	0.1	ND	0.01	LC-MSMS	15	虫
20	アシフルオルフェン	ACIFLUORFEN	—(*0.01)	ND	0.05	LC-MSMS	15	豆
21	アシベンゾラル-S-メチル	ACIBENZOLAR-S-METHYL	0.05	ND	0.05	LC-MSMS	12	麦
22	アゾキシストロビン	AZOXYSTROBIN	0.02	ND	0.01	LC-MSD	15	豆
23	アジャラム	AZULAM	0.02	ND	0.02	LC-MSMS	15	豆
24	アジンホスメチル	AZINPHOS-METHYL	2	ND	0.01	GC-FPD	15	虫
25	アセタミプリド	ACETAMIPRID	0.2	ND	0.01	LC-MSMS	15	虫
26	アセトクロール	ACETOCHLOR	0.05	ND	0.01	GC-ECD	15	豆
27	アセフェート	ACEPHATE	0.5	ND	0.05	LC-MSMS	9	虫
28	アゾキシストロビン	AZOXYSTROBIN	0.1	ND	0.02	LC-MSMS	15	豆
29	アゾシクロチン及びシヘキサチン	AZOCYCLOTIN, CYHEXATIN	ND(0.02)	ND	0.02	LC-MSMS	4-5	虫
30	アトラジン	ATRAZINE	0.2	ND	0.01	GC-MSD	15	豆
31	アニロホス	ANILOFOS	—(*0.01)	ND	0.01	GC-FPD	15	豆
32	アバメクチン	ABAMECTIN	0.01	ND	0.01	LC-MSMS	15	虫
33	アミトラズ	AMITRAZ	0.05	ND	0.05	LC-MSMS	15	虫
34	アミトロール	AMITROLE	ND(0.025)	ND	0.02	LC-MSMS	4-5	米
35	アメトリン	AMETHYN	0.3	ND	0.01	LC-MSMS	15	豆
36	アラクロール	ALACHLOR	0.2	ND	0.01	GC-ECD	9	麦
37	アラニカルブ	ALANYCARB	—(*0.01)	ND	0.02	LC-MSMS	15	虫
38	アラマイト	ARAMITE	0.01	ND	0.01	LC-MSMS	15	果
39	アルジカルブ	ALDICARB	0.05	ND	0.01	LC-MSD	1	虫
40	アルドキシカルブ	ALDOXYCARB	—(*0.01)	ND	0.02	LC-MSD	15	果
41	アルドリン及びディルドリン	ALDRIN, DIELDRIN	ND(0.005)	ND	0.005	GC-ECD	9	虫
42	イオドスルフロンメチル	IODOSULFURON-METHYL	0.03	ND	0.01	LC-MSD	15	麦
43	イソキサフェンエチル	ISOXADIFEN-ETHYL	0.08	ND	0.01	LC-MSMS	15	豆
44	イソキサチオン	ISOXATHION	0.02	ND	0.01	GC-MSD	15	虫
45	イソキサフルトール	ISOXAFLUTOLE	0.1	ND	0.01	LC-MSMS	15	豆
46	イソフェンホス	ISOFENPHOS	0.02	ND	0.01	GC-FPD	9	虫
47	イソプロカルブ	ISOPROCARB	—(*0.01)	ND	0.01	LC-MSD	15	虫
48	イソプロチオラン	ISOPROTHIOLANE	—(*0.01)	ND	0.03	GC-ECD	15	茶・緑
49	イナベンフィド	INABENFIDE	—(*0.01)	ND	0.01	LC-MSMS	15	梨
50	イプロジオン	IPRODIONE	10	ND	0.01	GC-ECD	4-5	茶
51	イマザメタベンズメチルエステル	IMAZAMETHABENZ METHYL ESTER	—(*0.01)	ND	0.04	LC-MSMS	15	豆
52	イマザリル	IMAZALIL	0.05	ND	0.01	GC-MSD	9	果
53	イマゾスルフロン	IMAZOSULFURON	—(*0.01)	ND	0.01	LC-MSD	15	豆
54	イミダクロプリド	IMIDACLOPRID	0.1	ND	0.02	LC-MSD	15	虫
55	イミノクタジン	IMINOCTADINE	0.02	ND	0.03	GC-ECD	10	麦
56	イミベンコナゾール	IMIBENCONAZOLE	(*0.01)	ND	0.02	LC-MSMS	15	麦
57	インダノファン	INDANOFAN	—(*0.01)	ND	0.01	LC-MSMS	15	茶
58	インドキサカルブ	INDOXACARB	0.02	ND	0.02	LC-MSMS	15	虫
59	ウニコナゾール P	UNICONAZOLE-P	—(*0.01)	ND	0.02	LC-MSMS	15	麦
60	エスプロカルブ	ESPROCARB	—(*0.01)	ND	0.01	GC-MSD	15	茶

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NO.	Test Name(分析項目)		Japan 食品衛生法	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	告示	法
61	エタルフルラリン	ETHALFLURALIN	一律0.01	ND	0.01	GC-ECD	15	農
62	エチオフェンカルブ	ETHIOFENCARB	1.0	ND	0.01	LC-MSD	1	農
63	エチオン	ETHION	一律0.01	ND	0.01	GC-FPD	16	農
64	エチクロゼート	ETHYCLOZATE	0.05	ND	0.01	LC-MSMS	16	農
65	エチプロール	ETHIPROLE	0.02	ND	0.01	LC-MSMS	16	農
66	エディフェンホス	EDIFENPHOS	一律0.01	ND	0.01	GC-FPD	16	農
67	エテポン	ETHEPHON	0.5	ND	0.05	GC-FPD	16	農
68	エトキサゾール	ETOXAZOLE	一律0.01	ND	0.05	GC-MSD	15	農
69	エトフェンプロックス	ETOFENPROX	0.5	ND	0.01	GC-MSD	7	農
70	エトプロホス	ETHOPROPHOS	0.02	ND	0.005	LC-MSMS	2	農
71	エトベンザニド	ETOBENZANID	一律0.01	ND	0.01	GC-ECD	15	農
72	エトリジアゾール	ETRIDIAZOLE	0.1	ND	0.05	GC-ECD	15	農
73	エトリムホス	ETHRIMUS	一律0.01	ND	0.01	GC-FPD	16	農
74	エポキシコナゾール	EPOXICONAZOLE	一律0.01	ND	0.01	GC-MSD	16	農
75	エマメクチン安息香酸塩	EMAMECTIN BENZOATE	0.1	ND	0.01	LC-MSMS	16	農
76	エンドスルファン	ENDOSULFAN	0.1	ND	0.01	GC-ECD	15	農
77	エンドリン	ENDRIN	ND(0.005)	ND	0.005	GC-ECD	8	農
78	オキサジキシル	OXADIXYL	0.1	ND	0.1	LC-MSMS	15	農
79	オキサジクロメホン	OXAZICLOMEFONE	0.02	ND	0.01	LC-MSMS	15	農
80	オキサミル	OXAMYL	0.05	ND	0.01	LC-MSD	1	農
81	オキシフルオルフェン	OXYFLUORFEN	0.05	ND	0.01	GC-MSD	15	農
82	オメトエート	OMETHOATE	2	ND	0.02	GC-FPD	16	農
83	オリザリン	ORYZALIN	0.01	ND	0.01	LC-MSMS	16	農
84	カフェンストロール	CAFENSTROLE	一律0.01	ND	0.01	LC-MSMS	16	農
85	カプタホール	CAPTAFOL	ND(0.01)	ND	0.01	LC-MSMS	7	農
86	カルタップ、チオシクラム、及びベンスルタップ(遊離として)	CARTAP,THIOCYCLAM & BENSULTAP (as free)	0.2	ND	0.05	LC-MSMS	15	農
87	カルバリル	CARBARYL	0.1	ND	0.01	LC-MSD	15	農・医
88	カルフェントラゾンエチル	CARFENTRAZONE-ETHYL	0.06	ND	0.01	GC-MSD	16	農
89	カルプロパミド	CARPROPAMID	0.1	ND	0.01	GC-MSD	15	農
90	カルベンダジム、ベノミル及びチオファネートメチル	CARBENDAZIM, BENOMYL, THIOPHANATE-METHYL	0.7	ND	0.02	LC-MSMS	16	農
91	カルボキシン	CARBOXIN	0.2	ND	0.01	GC-MSD	16	農
92	カルボスルファン	CARBOSULFAN	0.05	ND	0.01	GC-MSD	16	農
93	カルボフラン	CARBOFURAN	0.05	ND	0.01	LC-MSD	16	農
94	キザロホップエチル	QUIZALOFOP-ETHYL	0.01	ND	0.01	GC-MSD	15	農
95	キナルホス	QUINALPHOS	0.05	ND	0.01	GC-FPD	15	農
96	キノクラミン	QUINOCLAMINE	一律0.01	ND	0.01	LC-MSMS	15	農
97	キノメチオナート	QUINOMETHIONAT	0.1	ND	0.02	LC-MSMS	1	農
98	キャプタン	CAPTAN	10	ND	0.01	GC-ECD	15	農
99	キントゼン	QUINTOZENE	0.01	ND	0.01	GC-MSD	16	農
100	クミルロン	CUMYLURON	0.02	ND	0.02	LC-MSMS	15	農
101	グリホサート	GLYPHOSATE	1	ND	0.02	GC-MSD	1	農
102	グルホシネート	GLUFOSINATE	0.1	ND	0.02	GC-MSD	2	農
103	クレソキシムメチル	KRESOXIM-METHYL	5	ND	0.01	GC-MSD	16	農
104	クレトジム	CLETHODIM	1	ND	0.02	LC-MSMS	16	農
105	クロジナホッププロパルギル	CLODINAFOP-PROPARGYL	0.02	ND	0.01	LC-MSMS	15	農
106	クロジナホップ酸	CLODINAFOP ACID	一律0.01	ND	0.05	LC-MSMS	15	農
107	クロゾリネート	CHLOZOLINATE	0.06	ND	0.05	GC-MSD	15	農
108	クロチアニジン	CLOTHIANIDIN	0.02	ND	0.01	LC-MSMS	17	農
109	クロピラリド	CLOPYRALID	2	ND	0.5	LC-MSMS	15	農
110	クロフェンテジン	CLOFENTEZINE	0.05	ND	0.01	LC-MSMS	11	農
111	クロメプロップ	CLOMEPROP	一律0.01	ND	0.02	LC-MSMS	16	農
112	クロルアトキシホス	CHLORETHOXYFOS	0.01	ND	0.01	GC-AED	15	農
113	クロルクールジメチル	CHLORTHAL-DIMETHYL	3	ND	0.01	LC-MSMS	15	農
114	クロルデン	CHLORDANE	0.02	ND	0.01	GC-ECD	15	農
115	クロルピリホス	CHLORPYRIFOS	0.1	ND	0.01	GC-FPD	1	農
116	クロルピリホスメチル	CHLORPYRIFOS-METHYL	7	ND	0.01	GC-FPD	15	農
117	クロルフェナピル	CHLORFENAPYR	0.05	ND	0.01	GC-ECD	15	農
118	クロルフェンソン	CHLORFENSON	0.01	ND	0.01	GC-ECD	15	農
119	クロルフェンビンホス	CHLORFENVINPHOS	0.05	ND	0.01	GC-FPD	4・5	農
120	クロルフファム	CHLORBUFAM	0.05	ND	0.01	GC-MSD	15	農
121	クロルフルアゾロン	CHLORFLUAZURON	0.05	ND	0.01	LC-MSD	15	農

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NO.	Test Name(分析項目)		Japan 食品衛生法	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	倍率	系
122	クロルプロファム	CHLORPROPHAM	0.05	ND	0.01	GC-MSD	1	除草剤
123	クロルベンジド	CHLORBENZIDE	0.01	ND	0.01	GC-ECD	15	殺虫
124	クロルメコート	CHLORMEQUAT	0.05	ND	0.02	LC-MSMS	15	調
125	クロロクスロン	CHLOROXURON	0.05	ND	0.05	LC-MSMS	15	除草
126	クロロタロニル	CHLOROTHALONIL	0.01	ND	0.01	GC-ECD	15	殺菌
127	クロロネブ	CHLORONEB	一律0.01	ND	0.03	GC-ECD	15	殺菌
128	クロロベンジレート	CHLOROBENZILATE	0.02	ND	0.01	GC-MSD	15	殺虫
129	シアナジン	CYANAZINE	0.1	ND	0.01	LC-MSMS	12	除草
130	シアノホス	CYANOPHOS	一律0.01	ND	0.01	GC-FPD	15	殺虫
131	シアフェンチウロン	CYAFENTRIURON	0.02	ND	0.1	GC-MSD	15	殺虫
132	シアン化水素	HYDROGEN CYANIDE	20	ND	5	GC-NPD	15	燻蒸
133	ジクロン	DIURON	0.7	ND	0.01	LC-MSMS	15	除草
134	ジエトフェンカルブ	DIETHOFENCARB	一律0.01	ND	0.03	GC-MSD	15	殺菌
135	ジオキサチオン	DIOXATHION	0.06	ND	0.01	GC-FPD	15	殺虫
136	ジカンバ	DICAMBA	0.6	ND	0.02	LC-MSMS	6	除草
137	シクラニリド	CYCLANILIDE	一律0.01	ND	0.01	LC-MSMS	15	除
138	ジクロシメット	DICLOCYMET	一律0.01	ND	0.01	GC-ECD	15	殺
139	ジクロスラム	DICLOSULAM	一律0.01	ND	0.02	LC-MSMS	15	除草
140	シクロスルファムロン	CYCLOSULFAMURON	一律0.01	ND	0.01	LC-MSD	15	除草
141	ジクロフェンチオン	DICHLOFENTHION	一律0.01	ND	0.01	GC-FPD	15	殺虫
142	ジクロフルアニド	DICHLOFLUANID	5	ND	0.05	GC-MSD	15	殺菌
143	シクロプロトリン	CYCLOPROTHRIN	0.02	ND	0.05	LC-MSMS	15	殺虫
144	ジクロベニル	DICHLOBENIL	0.05	ND	0.05	GC-ECD	15	除草
145	ジクロホップメチル	DICLOFOP-METHYL	0.1	ND	0.01	GC-MSD	15	除草
146	ジクロルプロップ	DICHLORPROP	0.05	ND	0.02	LC-MSMS	15	除草
147	ジクロルボス、ナレド	DICHLORVOS, NALED	0.2	ND	0.01	GC-FPD	3	殺虫
148	ジクワット	DIQUAT	0.05	ND	0.02	LC-DAD	16	除草
149	ジコホール	DICOFOL	3	ND	0.01	GC-MSD	15	殺虫
150	ジスルホトン	DISULFOTON	0.02	ND	0.01	GC-FPD	15	殺虫
151	ジチオピル	DITHIOPYR	一律0.01	ND	0.01	GC-ECD	15	除草
152	ジニドンエチル	DINIDON-ETHYL	0.1	ND	0.01	LC-MSMS	15	除草
153	ジノカップ	DINOCAP	一律0.01	ND	0.01	LC-MSD	15	殺菌
154	シハロトリン	CYHALOTHRIN	0.04	ND	0.01	GC-MSD	15	殺虫
155	シハロホップブチル	CYHALOFOP-BUTYL	一律0.01	ND	0.03	GC-MSD	15	除草
156	ジフェノコナゾール	DIFENOCONAZOLE	0.1	ND	0.03	GC-MSD	7	殺菌
157	シフルトリン	CYFLUTHRIN	2	ND	0.03	GC-MSD	4~5	殺虫
158	シフルフェナミド	CYFLUFENAMID	1	ND	0.01	GC-MSD	15	殺菌
159	ジフルフェニカン	DIFLUFENICAN	0.1	ND	0.01	GC-MSD	15	除草
160	ジフルベンズロン	DIFLUBENZURON	2	ND	0.01	LC-MSMS	15	殺虫
161	シプロコナゾール	CYPROCONAZOLE	0.1	ND	0.01	GC-MSD	8	殺菌
162	シプロジニル	CYPRODINIL	0.5	ND	0.01	LC-MSMS	12	殺菌
163	シペルメトリン	CYPERMETHRIN	0.2	ND	0.05	GC-MSD	1	殺虫
164	シマジン	SIMAZINE	0.3	ND	0.05	GC-MSD	15	除草
165	シメコナゾール	SIMEOCONAZOLE	一律0.01	ND	0.01	LC-MSMS	15	殺菌
166	ジメタメトリン	DIMETHAMETRYN	一律0.01	ND	0.01	LC-MSMS	16	除草
167	ジメタピン	DIMETHIPIN	0.04	ND	0.01	GC-ECD	15	調
168	ジメチリモール	DIMETHIRIMOL	一律0.01	ND	0.05	LC-MSMS	15	殺菌
169	ジメチルビンホス	DIMETHYLVINPHOS	一律0.01	ND	0.01	GC-FPD	15	殺虫
170	ジメテナミド	DIMETHENAMID	0.1	ND	0.02	GC-ECD	8	除草
171	ジメトエート	DIMETHOATE	1	ND	0.01	GC-FPD	15	殺虫
172	ジメトリン	DIMETRYN	一律0.01	ND	0.02	GC-MSD	15	除草
173	ジメピペレート	DIMEPIPERATE	一律0.01	ND	0.01	GC-MSD	15	除草
174	シモキサニル	CYMOXANIL	0.05	ND	0.02	LC-MSD	15	殺菌
175	シロマジン	CYROMAZINE	0.3	ND	0.05	LC-MSMS	15	殺虫
176	シンメチリン	SIMMETHYLIN	一律0.01	ND	0.01	GC-MSD	15	除草
177	スピノサド	SPINOSAD	0.02	ND	0.01	LC-MSMS	14	殺虫
178	スピロキサミン	SPIROXAMINE	一律0.01	ND	0.01	GC-MSD	15	殺菌
179	スピロジクロフェン	SPIRODICLOFEN	一律0.01	ND	0.01	LC-MSMS	16	殺虫
180	スルフェントラゾン	SULFENTRAZONE	0.2	ND	0.01	LC-MSD	15	除草
181	スルプロホス	SULPROFOS	一律0.01	ND	0.01	GC-ECD	15	殺虫
182	セトキシジム	SETHOXYDIM	0.2	ND	0.05	GC-MSD	2	除草
183	テーバシル	TERBACIL	一律0.01	ND	0.05	LC-MSMS	15	除

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USDA Accredited Lab No. 4177
Registered Lab of MHLW, Japan / KFDA, Korea
Registered ISO 9001 : 2000 Laboratory

NO.	Test Name(分析項目)		Japan 食品衛生局	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	備考	系
184	ダイアジノン	DIAZINON	0.02	ND	0.01	GC-FPD	15	殺虫
185	ダイアレート	DI-ALLATE	0.03	ND	0.02	GC-ECD	16	除草
186	ダイムロン	DAIMURON	一律0.01	ND	0.01	LC-MSMS	15	除草
187	ダゾメット、メタム及び メチルイソチオシアネート(総和として)	DAZOMET, METHAM & METHYL-ISOTHIOCYANATE	一律0.01	ND	0.05	GC-MSD	15	殺菌
188	ダミノジット	DAMINOZIDE	ND(0.1)	ND	0.1	GC-MSD	1	調査
189	チアクロプリド	THIACLOPRID	一律0.01	ND	0.02	LC-MSMS	15	殺虫
190	チアジニル	TIADINIL	一律0.01	ND	0.01	LC-MSMS	16	殺菌
191	チアベンダゾール	THIABENDAZOLE	0.05	ND	0.05	LC-MSMS	16	殺虫
192	チアメトキサム	THIAMETHOXAM	0.02	ND	0.01	LC-MSMS	15	殺虫
193	チオジカルブ及びメソミル	THIODICARB, METHOMYL	0.02	ND	0.01	LC-MSD	16	殺虫
194	チオベンカルブ	THIOBENCARB	0.1	ND	0.01	GC-ECD	3	除草
195	チオメトン	THIOMETON	0.02	ND	0.01	GC-AED	4+9	殺虫
196	チジアズロン	THIDIAZURON	一律0.01	ND	0.03	LC-MSMS	15	植調
197	チフェンスルフロンメチル	THIFENSULFURON METHYL	0.1	ND	0.01	LC-MSD	15	除草
198	チフルザミド	THIFLUZAMIDE	一律0.01	ND	0.02	GC-ECD	16	殺菌
199	テクナゼン	TECNAZENE	0.05	ND	0.01	GC-ECD	15	殺菌
200	テトラクロルビンホス	TETRACHLORVINPHOS	一律0.01	ND	0.01	GC-FPD	18	殺虫
201	テトラコナゾール	TETRACONAZOLE	一律0.01	ND	0.01	GC-MSD	16	殺菌
202	テトラジホン	TETRADIFON	5	ND	0.01	GC-ECD	15	殺虫
203	テニルクロール	THENYLCHLOR	一律0.01	ND	0.01	GC-FPD	16	除草
204	テブコナゾール	TEBUCONAZOLE	0.05	ND	0.03	GC-MSD	8	殺菌
205	テブフェノジド	TEBUFENOZIDE	5	ND	0.05	LC-MSMS	15	殺虫
206	テブフェンピラド	TEBUFENPYRAD	一律0.01	ND	0.01	GC-MSD	16	殺虫
207	テフルトリン	TEFLUTHRIN	0.1	ND	0.02	GC-MSD	7	殺虫
208	テフルベンズロン	TEFLUBENZURON	0.1	ND	0.02	LC-MSMS	9	殺虫
209	デメトン-S-メチル	DEMETON-S-METHYL	0.4	ND	0.01	GC-FPD	15	殺虫
210	デルタメトリン及びトラロメトリン	DELTAMETHRIN, TRALOMETHRIN	1.0	ND	0.03	GC-MSD	1	殺虫
211	テルブトリン	TERBUTRYN	0.1	ND	0.02	GC-MSD	10	除草
212	テルブホス	TERBUFOS	0.01	ND	0.005	GC-FPD	3	殺虫
213	テレフタル酸銅	COPPER TELEPHTALATE	0.5	ND	0.3	LC-MSMS	15	殺菌
214	トラルコキシジム	THALKOXYDIM	0.02	ND	0.01	LC-MSMS	16	除草
215	トリアジメノール	TRIADIMENOL	0.1	ND	0.01	LC-MSMS	15	殺菌
216	トリアジメホン	TRIADIMEFON	0.1	ND	0.01	GC-MSD	16	殺菌
217	トリアスルフロン	TRIASULFURON	0.02	ND	0.01	LC-MSD	16	除草
218	トリアゾホス	TRIAZOPHOS	ND(0.05)	ND	0.01	GC-FPD	14	殺虫
219	トリアレート	TRI-ALLATE	0.05	ND	0.01	GC-ECD	16	除草
220	トリクロピル	TRICLOPYR	0.03	ND	0.02	LC-MSMS	15	除草
221	トリクロルホン	TRICHLORFON	0.1	ND	0.01	GC-ECD	1	殺虫
222	トリチコナゾール	TRITICONAZOLE	0.05	ND	0.01	LC-MSMS	16	殺菌
223	トリデモルフ	TRIDEMORPH	0.05	ND	0.01	LC-MSMS	15	殺菌
224	トリブホス	TRIBUPHOS	一律0.01	ND	0.01	GC-FPD	16	調査
225	トリフルミゾール	TRIFLUMIZOLE	1	ND	0.01	GC-ECD	2	殺菌
226	トリフルムロン	TRIFLUMURON	0.05	ND	0.02	LC-MSMS	15	殺虫
227	トリフルラリン	TRIFLURALIN	0.05	ND	0.01	GC-ECD	8	除草
228	トリフロキシストロビン	TRIFLOXYSTROBIN	0.05	ND	0.02	LC-MSMS	16	殺菌
229	トリフロキシスルフロン	TRIFLOXYSULFURON	一律0.01	ND	0.01	LC-MSD	16	除草
230	トリベヌロンメチル	TRIBENURON-METHYL	0.05	ND	0.05	LC-MSMS	16	除草
231	トルクロホスメチル	TOLCLOFOS-METHYL	0.1	ND	0.01	GC-FPD	8	殺菌
232	ナプロアニリド	NAPROANILIDE	一律0.01	ND	0.01	GC-MSD	16	除草
233	ナプロパミド	NAPROPAMIDE	一律0.01	ND	0.01	GC-MSD	16	除草
234	ニコチン	NICOTINE	2	ND	0.02	GC-MSD	15	殺虫
235	ノバルロン	NOVALURON	0.02(一律0.01)	ND	0.01	LC-MSMS	16+(16)	殺虫
236	ノルフルラゾン	NORFLURAZON	一律0.01	ND	0.03	GC-MSD	15	除草
237	バミドチオン	VAMIDOTHION	0.2	ND	0.03	GC-FPD	11	殺虫
238	パラコート	PARAQUAT	0.1	ND	0.02	LC-DAD	15	除草
239	パラチオン	PARATHION	0.3	ND	0.01	GC-FPD	0	殺虫
240	パラチオンメチル	PARATHION-METHYL	1	ND	0.01	GC-FPD	1	殺虫
241	ハロキシホップ	HALOXYFOP	一律0.01	ND	0.01	GC-MSD	15	除草
242	ハロスルフロンメチル	HALOSULFURON METHYL	0.1	ND	0.01	LC-MSD	14	除草
243	ビオレスメトリン	BIORESMETHRIN	1	ND	0.05	GC-MSD	14	殺虫
244	ピコリナフェン	PICOLINAFEN	0.02	ND	0.01	LC-MSMS	18	除草
245	ビテルタノール	BITERTANOL	0.05	ND	0.01	LC-MSMS	2	殺菌
246	ビフェナゼート	BIFENAZATE	0.02(一律0.01)	ND	0.05	LC-MSMS	15+(19)	殺虫
247	ビフェノックス	DIFENOX	一律0.01	ND	0.01	GC-ECD	15	殺菌

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NO.	Test Name(分析項目)		Japan 食品衛生法	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	告示	系
240	ビフェントリン	BIFENTHRIN	0.05	ND	0.01	GC-MSD	8	殺
249	ピペロニルブトキシド	PIPERONYL BUTOXIDE	24	ND	0.02	GC-MSD	15	調
250	ピペロホス	PIPEROPHOS	—(仲)0.01	ND	0.01	GC-FPD	15	除
251	ヒメキサゾール	HYMEXAZOL	0.02	ND	0.02	LC-MSMS	15	殺
252	ピメトロジン	PYMETROZINE	—(仲)0.01	ND	0.01	LC-MSMS	15	殺
253	ピラクロストロビン	PYRACLOSTROBIN	0.1	ND	0.01	LC-MSMS	16	殺
254	ピラゾホス	PYRAZOPHOS	0.05	ND	0.01	GC-FPD	15	殺
255	ピラゾリネート	PYRAZOLYNATE	0.02	ND	0.01	LC-MSMS	15	除
256	ピラフルフェンエチル	PYRAFLUFEN-ETHYL	0.1	ND	0.03	GC-MSD	18	除・調
257	ピリダフェンチオン	PYRIDAFENTHION	—(仲)0.01	ND	0.01	GC-FPD	15	殺
258	ピリダベン	PYRIDABEN	—(仲)0.01	ND	0.01	GC-ECD	15	殺
259	ピリダリル	PYRIDALYL	0.02	ND	0.01	LC-MSMS	15	殺
260	ピリフタリド	PYRIFTALID	—(仲)0.01	ND	0.05	LC-MSMS	15	除
261	ピリブチカルブ	PYRIBUTICARB	—(仲)0.01	ND	0.01	GC-MSD	15	除
262	ピリプロキシフェン	PYRIPROXYFEN	0.0	ND	0.01	GC-MSD	15	殺
263	ピリミカーブ	PIRIMICARB	0.05	ND	0.01	GC-MSD	1	殺
264	ピリミノバックメチル	PYRIMINOBAC-METHYL	—(仲)0.01	ND	0.01	GC-MSD	15	除
265	ピリミホスメチル	PIRIMIPHOS-METHYL	1	ND	0.01	GC-FPD	4-5	殺
266	ピレトリン	PYRETHRIN	3	ND	0.1	GC-MSD	3	殺
267	ピロキロン	PYROQUILON	—(仲)0.01	ND	0.01	GC-MSD	15	防
268	ビンクロゾリン	VINCLOZOLIN	—(仲)0.01	ND	0.01	GC-MSD	15	殺
269	ファモキサドン	FAMOXADONE	—(仲)0.01	ND	0.02	LC-MSD	15	殺
270	フィプロニル	FIPRONIL	0.02	ND	0.002	LC-MSMS	14	殺
271	フェナミホス	FENAMIPHOS	0.02	ND	0.01	GC-FPD	15	殺
272	フェナリモル	FENARIMOL	0.1	ND	0.01	GC-MSD	6	殺
273	フェニトロチオン	FENITROTHION	1	ND	0.01	GC-FPD	1	殺
274	フェノキサニル	FENOXANIL	—(仲)0.01	ND	0.01	LC-MSMS	15	殺
275	フェノキサプロップエチル	FENOXAPROP-ETHYL	—(仲)0.01	ND	0.01	GC-MSD	15	除
276	フェノチオカルブ	FENOTHIOCARB	—(仲)0.01	ND	0.01	LC-MSMS	15	殺
277	フェノブカルブ	FENOBUCARB	0.3	ND	0.01	LC-MS	4-6	殺
278	フェリムゾン	FERIMZONE	—(仲)0.01	ND	0.01	LC-MSMS	15	除
279	フェンクロルホス	FENCHLORPHOS	0.01	ND	0.01	GC-FPD	15	殺
280	フェンスルホチオン	FENSULFOTHION	0.1	ND	0.01	GC-FPD	1	殺
281	フェンチオン	FENTHION	5	ND	0.01	GC-FPD	15	殺
282	フェンチン	FENTIN	0.05	ND	0.02	LC-MSMS	14	殺
283	フェントエート	PHENTHOATE	0.4	ND	0.01	GC-FPD	15	殺
284	フェントラザミド	FENTRAZAMIDE	—(仲)0.01	ND	0.01	LC-MSMS	15	除
285	フェンバレレート	FENVALERATE	2	ND	0.05	GC-MSD	4-6	殺
286	フェンピロキシメート	FENPYROXIMATE	0.02	ND	0.02	LC-MSMS	15	殺
287	フェンブコナゾール	FENBUCONAZOLE	—(仲)0.01	ND	0.02	LC-MSMS	15	殺
288	フェンプロパトリン	FENPROPATHRIN	—(仲)0.01	ND	0.01	GC-MSD	15	殺
289	フェンプロピモルフ	FENPROPIMORPH	0.3	ND	0.01	GC-MSD	15	殺
290	ブタクロール	BUTACHLOR	—(仲)0.01	ND	0.01	GC-MSD	15	除
291	ブタフェナシル	BUTAFENACIL	0.02	ND	0.01	GC-MSD	15	除
292	ブタミホス	BUTAMIFOS	—(仲)0.01	ND	0.01	GC-FPD	15	除
293	ブチレート	BUTYLATE	0.1	ND	0.01	GC-MSD	8	除
294	ブプロフェジン	BUPROFEZIN	0.5	ND	0.01	GC-MSD	15	殺
295	フラチオカルブ	FURATHIOCARB	0.05	ND	0.01	LC-MSMS	16	殺
296	フラムプロップメチル	FLAMPROP-METHYL	—(仲)0.01	ND	0.01	GC-MSD	15	除
297	プリミスルフロンメチル	PRIMISULFURON-METHYL	0.06	ND	0.01	LC-MSD	16	除
298	フリラゾール	FURILAZOLE	0.01	ND	0.01	GC-ECD	15	殺
299	フルアジナム	FLUAZINAM	—(仲)0.01	ND	0.05	LC-MSMS	16	殺・調
300	フルアジホップ	FLUAZIFOP	—(仲)0.01	ND	0.01	GC-MSD	16	除
301	フルオメツロン	FLUOMETURON	0.1	ND	0.02	LC-MSMS	15	除
302	フルキンコナゾール	FLUQUINCONAZOLE	—(仲)0.01	ND	0.01	GC-MSD	16	殺
303	フルジオキソニル	FLUDIOXONIL	0.02	ND	0.01	LC-MSMS	8	殺
304	フルシトリネート	FLUCYTHRINATE	0.05	ND	0.02	GC-MSD	1	殺
305	フルシラゾール	FLUSILAZOLE	—(仲)0.01	ND	0.01	GC-MSD	15	殺
306	フルアアセットメチル	FLUTHIACET-METHYL	0.1	ND	0.03	LC-MSMS	15	除
307	フルトラニル	FLUTOLANIL	—(仲)0.01	ND	0.01	GC-MSD	15	殺
308	フルトリアホール	FLUTRIAFOL	0.02	ND	0.01	LC-MSMS	15	殺
309	フルバリネート	FLUVALINATE	—(仲)0.01	ND	0.01	GC-MSD	16	殺
310	フルフェナセット	FLUFENACET	0.05	ND	0.01	GC-MSD	16	除
311	フルフェノクスロン	FLUFENOXURON	0.02	ND	0.01	LC-MSMS	15	殺
312	フルフェンピルエチル	FLUFENPYR-ETHYL	0.01	ND	0.01	LC-MSMS	15	除
313	フルミオキサジン	FLUMIOXAZIN	0.05	ND	0.03	LC-MSMS	16	除

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NO.	Test Name(分析項目)		Japan 食品用器具	Result 検査結果	LOQ 定量限界値	Instrument 分析方法	告示	法
314	フルミクロラックペンチル	FLUMICLORAC PENTYL	0.01	ND	0.02	LC-MSMS	15	薬
315	フルリドン	FLURIDONE	0.1	ND	0.01	LC-MSMS	15	薬
316	フルロキシピル	FLUROXYPYR	0.1	ND	0.01	LC-MSMS	15	薬
317	プレナクロール	PRETILACHLOR	一律0.01	ND	0.01	GC-MSD	16	農
318	プロクロラズ	PROCHLORAZ	2	ND	0.01	GC-MSD	15	農
319	プロシミドン	PROCYMIDONE	0.02	ND	0.02	GC-MSD	16	農
320	プロスルフロン	PROSULFURON	0.01	ND	0.01	LC-MSD	15	薬
321	プロチオホス	PROTHIOFOS	一律0.01	ND	0.01	GC-FPD	16	殺
322	プロパキザホップ	PROPAQUIZAFOP	一律0.01	ND	0.01	LC-MSMS	15	薬
323	プロパクロール	PROPACHLOR	0.09	ND	0.01	GC-MSD	16	薬
324	プロパジン	PROPAZINE	一律0.01	ND	0.01	GC-MSD	15	薬
325	プロパニル	PROPANIL	一律0.01	ND	0.01	GC-MSD	16	薬
326	プロパホス	PROPAPHOS	一律0.01	ND	0.01	GC-FPD	15	殺
327	プロパルギット	PROPARGITE, BPPS	0.1	ND	0.01	GC-MSD	15	殺
328	プロピコナゾール	PROPICONAZOLE	1	ND	0.03	GC-MSD	3	農
329	プロピザミド	PROPYZAMIDE	0.02	ND	0.01	LC-MSMS	16	薬
330	プロファム	PROPHAM	ND(0.01)	ND	0.01	LC-MSMS	15	殺・調
331	プロフェノホス	PROFENOFOS	0.05	ND	0.01	GC-FPD	16	殺
332	プロヘキサジオンカルシウム塩	PROHEXADIONE CALCIUM	0.2	ND	0.1	LC-MSMS	7	調
333	プロポキスル(プロポクスル)	PROPOXUR	0.5	ND	0.01	LC-MSD	15	殺
334	ブロマシル	BROMACIL	一律0.01	ND	0.02	LC-MSMS	16	除
335	ブロメトリン	PROMETRYN	0.2	ND	0.02	GC-MSD	15	除
336	ブロモキシニル	BROMOXYNIL	0.2	ND	0.03	LC-MSMS	15	薬
337	ブロモブチド	BROMOBUTIDE	一律0.01	ND.	0.01	GC-MSD	16	除
338	ブロモプロピレート	BROMOPROPYLATE	0.05	ND	0.01	GC-MSD	15	殺
339	ブロモホスエチル	BROMOPHOS-ETHYL	0.05	ND	0.01	GC-ECD	16	殺
340	ヘキサクロロベンゼン	HEXACHLOROBENZENE	0.03	ND	0.01	GC-ECD	15	農
341	ヘキサコナゾール	HEXACONAZOLE	0.02	ND	0.01	LC-MSMS	15	農
342	ヘキサフルムロン	HEXAFLUMURON	0.02	ND	0.01	LC-MSMS	16	殺
343	ヘキシチアゾックス	HEXYTHIAZOX	0.05	ND	0.02	LC-MSMS	15	殺
344	ベナラキシル	BENALAXYL	0.05	ND	0.01	GC-MSD	16	農
345	ベノキサコール	BENOXACOR	0.01	ND	0.01	GC-ECD	15	薬
346	ヘプタクロル	HEPTACHLOR	0.02	ND	0.01	GC-ECD	16	殺
347	ペルメトリン	PERMETHRIN	2	ND	0.02	GC-MSD	1	殺
348	ペンコナゾール	PENCONAZOLE	0.03	ND	0.01	GC-MSD	15	農
349	ペンシクロン	PENCYCURON	0.1	ND	0.01	LC-MSMS	16	農
350	ペンスリド	BENSULIDE	0.03	ND	0.02	LC-MSMS	15	除
351	ベンゾビシクロン	BENZOBICYCLON	一律0.01	ND	0.02	LC-MSMS	16	除
352	ベンゾフェナップ	BENZOFENAP	一律0.01	ND	0.01	LC-MSMS	16	薬
353	ベンディオカルブ	BENDIOCARB	0.02	ND	0.01	LC-MSD	1	殺
354	ベンタゾン	BENTAZONE	0.2	ND	0.02	LC-MSMS	3	除
355	ペンディメタリン	PENDIMETHALIN	0.2	ND	0.02	GC-MSD	2	除・調
356	ペントキサゾン	PENTOXAZONE	一律0.01	ND	0.01	GC-ECD	16	除
357	ベンフラカルブ	BENFURACARB	0.05	ND	0.01	LC-MSD	15	殺
358	ベンフレセート	BENFURESATE	一律0.01	ND	0.01	GC-MSD	15	除
359	ホキシム	PHOXIM	0.03	ND	0.02	LC-MSMS	4・6	殺
360	ホサロン	PHOSALONE	一律0.01	ND	0.01	GC-FPD	15	殺
361	ボスカリド	BOSCALID	一律0.01	ND	0.01	GC-ECD	16	農
362	ホスチアゼート	FOSTHIAZATE	一律0.01	ND	0.01	GC-FPD	15	殺
363	ホスファミドン	PHOSPHAMIDON	0.1	ND	0.01	GC-FPD	15	殺
364	ホスメット	PHOSMET	0.05	ND	0.01	GC-FPD	16	殺
365	ホメサフェン	FOMESAFEN	一律0.01	ND	0.03	LC-MSMS	19	除
366	ホルモチオン	FORMOTHION	0.02	ND	0.02	GC-AED	16	殺
367	ホレート	PHORATE	0.05	ND	0.01	GC-FPD	16	殺
368	マラチオン	MALATHION	2	ND	0.01	GC-FPD	1	殺
369	マレイン酸ヒドラジド	MALEIC HYDRAZIDE	1	ND	0.2	LC-DAD	16	除・調
370	ミクロブタニル	MYCLOBUTANIL	0.03	ND	0.01	GC-MSD	15	農
371	ミルベメクチン	MILBEMECTIN	0.02	ND	0.05	LC-MSMS	16	殺
372	メカルバム	MECARBAM	0.05	ND	0.01	GC-FPD	15	殺
373	メコプロップ	MECOPROP	0.05	ND	0.02	LC-MSMS	16	除
374	メタクリホス	METHACRIFOS	0.05	ND	0.01	GC-FPD	16	殺
375	メタベンズチアズロン	METHABENZTHIAZURON	0.1	ND	0.01	GC-MSD	4	除
376	メタミドホス	METHAMIDOPHOS	0.1	ND	0.01	LC-MSMS	15	殺
377	メタラキシル及びメフェノキサム	METALAXYL, MEFENOXAM	0.03	ND	0.01	GC-MSD	16	農

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USDA Accredited Lab No. 4177
Registered Lab of MHLW, Japan / KFDA, Korea
Registered ISO 9001 : 2000 Laboratory

NO.	Test Name(分析項目)		Japan 食品用基準	Result 検出結果	LOQ 定量限界値	Instrument 分析方法	告示	系
378	メチオカルブ	METHIOCARB	0.05	ND	0.01	LC-MSD	4・5	殺
379	メチダチオン	METHIDATHION	0.1	ND	0.01	LC-MSMS	15	殺
380	メトキシクロール	METHOXYCHLOR	7	ND	0.01	GC ECD	15	殺
381	メトキシフェノジド	METHOXYFENOZIDE	0.02	ND	0.01	LC-MSMS	15	殺
382	メトスラム	METOSULAM	0.02	ND	0.01	LC-MSMS	15	除
383	メトプレン	METHOPRENE	5	ND	0.01	GC-MSD	1	殺
384	メトミノストロビン	METOMINOSTROBIN	一律0.01	ND	0.01	GC-MSD	15	殺
385	メトラクロール	METOLACHLOR	0.1	ND	0.01	GC-MSD	6	除
386	メトリブジン	METRIBUZIN	0.1	ND	0.01	GC-MSD	2	除
387	メピコートクロリド	MEPIQUAT CHLORIDE	2	ND	0.02	LC-MSMS	15	調
388	メビンホス	MEVINPHOS	一律0.01	ND	0.01	GC-FPD	13	殺
389	メフェナセット	MEFENACET	一律0.01	ND	0.05	LC-MSMS	15	除
390	メフェンピルジエチル	MEFENPYR-DIETHYL	0.01	ND	0.01	LC-MSMS	16	殺
391	メプロニル	MEPRONIL	一律0.01	ND	0.01	GC-MSD	18	殺
392	モノクロトホス	MONOCROTOPHOS	一律0.01	ND	0.01	GC-FPD	13	殺
393	モノリニュロン	MONOLINURON	0.06	ND	0.01	LC-MSMS	15	除
394	モリネート	MOLINATE	0.02	ND	0.01	GC-MSD	18	除
395	ラクトフェン	LACTOFEN	一律0.01	ND	0.02	LC-MSMS	15	除
396	リニュロン	LINURON	0.2	ND	0.02	LC-MSMS	15	除
397	リン化水素	HYDROGEN PHOSPHIDE	0.1	ND	0.02	GC-FPD	15	殺
398	ルフェヌロン	LUFENURON	0.05	ND	0.01	LC-MSMS	12	殺
399	レスメトリン	RESMETHRIN	0.1	ND	0.01	GC-MSD	15	殺
400	レナシル	LENACIL	一律0.01	ND	0.06	LC-MSMS	15	除
401	酸化フェンブタスズ	FENBUTATIN OXIDE	0.05	ND	0.02	LC-MSMS	13	殺
402	酸化プロピレン	PROPYLENE OXIDE	一律0.01	ND	0.000	GC-MSD	16	く
403	臭素	BROMIDE (INORGANIC BROMINE)	80	ND	1	GC-AED	1	く
404	二臭化エチレン	ETHYLENE DIBROMIDE	0.01	ND	0.005	GC-MSD	13	燻

ND: 検出せず

<告示・告示日・施行日一覧>

告示	0	従来から基準のあったもの	0	項目
告示	1	平成 4年 10月 27日告示分 (平成 6年 8月 1日施行)	0	項目
告示	2	平成 5年 3月 4日告示分 (平成 6年 8月 1日施行)	0	項目
告示	3	平成 3年 1月 14日告示分 (平成 4年 4月 1日施行)	0	項目
告示	4・5	平成 6年 6月 9日告示分 (平成 7年 1月 1日施行)	0	項目
告示	6	平成 7年 4月 14日告示分 (平成 8年 3月 1日施行)	0	項目
告示	7	平成 8年 6月 27日告示分 (平成 9年 3月 1日施行)	0	項目
告示	8	平成 9年 5月 1日告示分 (平成 10年 3月 1日施行)	0	項目
告示	9	平成10年 10月 12日告示分 (平成 11年 4月 1日施行)	0	項目
告示	10	平成11年 11月 22日告示分 (平成 12年 4月 1日施行)	0	項目
告示	11	平成12年 12月 4日告示分 (平成 12年12月 4日施行)	0	項目
告示	12	平成13年 2月 28日告示分 (平成 13年 4月 1日施行)	0	項目
告示	13	平成13年 7月 24日告示分 (平成 13年10月 1日施行)	0	項目
告示	14	平成14年 3月 13日告示分 (平成 14年 4月 1日施行)	0	項目
告示	15	平成17年 11月 28日告示分(平成18年 8月30日施行)	313	項目
告示	16	平成18年9月30日告示分(平成18年9月30日施行)	0	項目
告示	17	平成19年5月 31日告示分(平成19年5月31日施行)	0	項目
告示	18	平成19年5月 31日告示分(平成19年12月1日施行予定)	1	項目
告示	19	平成19年6月 28日告示分(平成19年10月28日施行予定)	1	項目

18,19は2007年8月現在未施行。

凡例 (殺)殺虫剤 (菌)殺菌剤 (除)除草剤 (燻)燻蒸剤 (く)くん蒸剤 (調)調味料 (他)その他

出典(食品衛生法第10条第 2004年8月15日発行)

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Accredited ISO/IEC 17025:2005

ORIGINAL

DATE: July 2, 2009
No. JF56Z00155B

CERTIFICATE OF ANALYSIS (分析証明書)

APPLICANT(申請者):	Japan Starch & Sweetners Industry Association/Japan Corn Grits Association (日本スターチ・糖化工業会/社団法人 日本コーングリッツ協会)
SAMPLE DESCRIPTION(サンプル):	US Maize 2008 Crop (2008年産アメリカ産トウモロコシ)
PLACE OF SAMPLING (サンプル採取場所):	HENNEPIN, IL, USA(アメリカ合衆国、イリノイ州、ヘネピン)
SAMPLED BY(サンプル採取者):	CGB
DATE OF SAMPLING (サンプル採取日):	June 11, 2009 (2009年6月11日)
CONDITION OF SAMPLE(サンプルの状態):	Plastic Bag (プラスチックバッグ入り)
SAMPLE DATE RECEIVED(受領日):	June 22, 2009 (2009年6月22日)

****

THIS IS TO CERTIFY that we, OMIC USA Inc., Portland, Oregon did carry out agricultural chemical residue analysis on the submitted sample with the above-mentioned details.
(OMIC USA Inc. で実施した上述の提出ｻﾝﾌﾟﾙの分析について次のとおり証明する)

PLACE AND DATE OF ANALYSIS (分析所及び分析日)

At the laboratory of OMIC USA Inc., Portland, Oregon between June 23, 2009 and July 2, 2009.
(分析場所：ｱﾒﾘｶ合衆国ｵﾚｺﾞﾝ州ﾎﾟｰﾄﾗﾝﾄﾞ市在 OMIC USA Inc. 分析期間：2009年6月23日～2009年7月2日)
OMIC USA Inc.は日本国厚生労働省の輸出国公的検査機関リストに指定検査機関(Registered laboratory)として登載されております。
(http://www.mhlw.go.jp/topics/yunyu/5/index.htmlをご参照ください。)

RESULTS (分析結果)

The contents of the required agricultural chemical residues and components are not detected and found as per the attached ANALYSIS RESULTS. (依頼を受けた農薬の検出結果は別紙のとおり)

This certificate refers to our intervention and findings at the time and place mentioned above only.

OMIC USA Inc.

President

Checked by K.Y.

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分析結果一覧表(厚生労働省 平成21年度残留農薬モニタリング433項目)

No	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
1	1,1-ジクロロ-2,2-ビス(4-エチルフェニル)エタン	1,1-DICHLORO-2,2-BIS-(4-ETHYLPHENYL)ETHANE	0.01	ND	0.03	GC-MSD	15	虫
2	2-(1-ナフチル)アセタミド	2-(1-NAPHTHYL)ACETAMIDE	一律0.01	ND	0.01	LC-MSMS	15	調
3	2,2-DPA	2,2-DPA	0.1	ND	0.1	GC-ECD	15	草
4	2,4,5-T	2,4,5-T	ND	ND	0.05	LC-MSMS	4・5	草
5	2,4-D	2,4-D	0.05	ND	0.02	LC-MSMS	10	草
6	2,4-DB	2,4-DB	0.02	ND	0.02	LC-MSMS	15	草
7	4-クロルフェノキシ酢酸	4-CPA	0.02	ND	0.01	LC-MSMS	15	調
8	BHC	BHC	0.2	ND	0.01	GC-ECD	0	虫
9	DCIP	DCIP	一律0.01	ND	0.02	GC-MSD	15	虫
10	DDT	DDT	0.2	ND	0.01	GC-ECD	0	虫
11	EPN	EPN	一律0.01	ND	0.01	GC-FPD	15	虫
12	EPTC	EPTC	0.1	ND	0.01	GC-MSD	8	草
13	MCPA	MCPA	0.1	ND	0.03	LC-MSMS	8	草・調
14	MCPB	MCPB	0.02	ND	0.02	LC-MSMS	15	草
15	TCMTB	TCMTB	0.1	ND	0.02	GC-MSD	15	菌
16	XMC	XMC	0.2	ND	0.01	LC-MSMS	15	虫
17	γ-BHC(リンデン)	gamma-BHC (LINDANE)	0.3	ND	0.01	GC-ECD	15	虫
18	アイオキシニル	IOXYNIL	0.1	ND	0.05	LC-MSMS	15	草
19	アクリナトリン	ACRINATHRIN	0.1	ND	0.01	GC-MSD	8	虫
20	アザコナゾール	AZACONAZOLE	一律0.01	ND	0.01	GC-ECD	15	菌
21	アザメチホス	AZAMETHIPHOS	0.1	ND	0.01	LC-MSMS	15	虫
22	アシフルオルフェン	ACIFLUORFEN	一律0.01	ND	0.05	LC-MSMS	15	草
23	アシベンゾラル-S-メチル	ACIBENZOLAR-S-METHYL	0.05	ND	0.05	LC-MSMS	12	菌
24	アジムスルフロン	AZIMSULFURON	0.02	ND	0.01	LC-MSD	15	虫
25	アシュラム	ASULAM	0.02	ND	0.02	LC-MSMS	15	草
26	アジンホスメチル	AZINPHOS-METHYL	2	ND	0.01	GC-FPD	15	虫
27	アセタミプリド	ACETAMIPRID	0.2	ND	0.01	LC-MSMS	15	虫
28	アセトクロール	ACETOCHLOR	0.05	ND	0.01	GC-ECD	15	草
29	アセフェート	ACEPHATE	0.5	ND	0.05	LC-MSMS	3	虫
30	アゾキシストロビン	AZOXYSTROBIN	0.05	ND	0.02	LC-MSMS	29	菌
31	アゾシクロチン及びシヘキサチン	AZOCYCLOTIN, CYHEXATIN	ND	ND	0.02	LC-MSMS	4・5	ダ
32	アトラジン	ATRAZINE	0.2	ND	0.01	GC-MSD	15	草
33	アニロホス	ANILOFOS	一律0.01	ND	0.01	GC-FPD	15	草
34	アバメクチン	ABAMECTIN	0.01	ND	0.01	LC-MSMS	15	虫
35	アミトラズ	AMITRAZ	0.05(一律0.01)	ND	0.01	LC-MSMS	32	ダ
36	アミトロール	AMITROLE	ND	ND	0.02	LC-MSMS	4・5	草
37	アメトリン	AMETRYN	0.3(0.05)	ND	0.01	LC-MSMS	33	草
38	アラクロール	ALACHLOR	0.2	ND	0.01	GC-ECD	9	草
39	アラニカルブ	ALANYCARB	一律0.01	ND	0.02	LC-MSMS	15	虫
40	アラマイト	ARAMITE	0.01	ND	0.01	LC-MSMS	15	ダ
41	アルジカルブ	ALDICARB	0.05	ND	0.01	LC-MSMS	1	虫
42	アルドキシカルブ	ALDOXYCARB	一律0.01	ND	0.02	LC-MSMS	15	虫
43	アルドリン及びディルドリン	ALDRIN, DIELDRIN	ND	ND	0.005	GC-ECD	0	虫
44	イオドスルフロンメチル	IODOSULFURON METHYL	0.03	ND	0.01	LC-MSD	15	草
45	イサゾホス	ISAZOPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
46	イソウロン	ISOURON	0.02	ND	0.02	LC-MSMS	15	草
47	イソキサジフェンエチル	ISOXADIFEN-ETHYL	0.09	ND	0.01	GC-MSD	15	草
48	イソキサチオン	ISOXATHION	0.02	ND	0.01	LC-MSMS	15	虫
49	イソキサフルトール	ISOXAFLUTOLE	0.1	ND	0.01	LC-MSMS	15	草
50	イソフェンホス	ISOFENPHOS	0.02	ND	0.01	GC-FPD	6	虫
51	イソプロカルブ	ISOPROCARB	一律0.01	ND	0.01	LC-MSMS	15	虫
52	イソプロチオラン	ISOPROTHIOLANE	一律0.01	ND	0.03	GC-MSD	15	菌・調
53	イナベンフィド	INABENFIDE	一律0.01	ND	0.01	LC-MSMS	15	調
54	イプロジオン	IPRODIONE	10	ND	0.01	GC-MSD	4・5	菌
55	イプロベンホス	IPROBENFOS	一律0.01	ND	0.01	GC-FPD	15	菌
56	イマザメタベンズメチルエステル	IMAZAMETHABENZ METHYL ESTER	一律0.01	ND	0.04	LC-MSMS	15	草
57	イマザリル	IMAZALIL	0.05	ND	0.01	GC-MSD	3	菌
58	イマゾスルフロン	IMAZOSULFURON	一律0.01	ND	0.01	LC-MSD	15	草
59	イミダクロプリド	IMIDACLOPRID	0.1	ND	0.02	LC-MSMS	15	虫
60	イミノクタジン	IMINOCTADINE	0.02	ND	0.05	GC-ECD	15	菌

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No.	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
61	イミベンコナゾール	IMIBENCONAZOLE	—(*0.01	ND	0.02	LC-MSMS	15	菌
62	インダノファン	INDANOFAN	(*0.01	ND	0.01	LC-MSMS	15	草
63	インドキサカルブ	INDOXACARB	0.02	ND	0.02	LC-MSMS	15	虫
64	ウニコナゾールP	UNICONAZOLE P	—(*0.01	ND	0.02	LC-MSMS	15	調
65	エスプロカルブ	ESPROCARB	—(*0.01	ND	0.01	GC-MSD	15	草
66	エタルフルラリン	ETHALFLURALIN	—(*0.01	ND	0.01	GC-ECD	15	草
67	エチオフェンカルブ	ETHIOFENCARB	1.0	ND	0.01	LC-MSMS	1	虫
68	エチオン	ETHION	—(*0.01	ND	0.01	GC-FPD	15	虫
69	エチクロゼート	ETHYCHLOZATE	0.05	ND	0.01	LC-MSMS	15	虫
70	エチプロール	ETHIPROLE	0.02(—(*0.01)	ND	0.01	LC-MSMS	33	虫
71	エディフェンホス	EDIFENPHOS	—(*0.01	ND	0.01	GC-FPD	15	菌
72	エテホン	ETHEPHON	0.5	ND	0.05	GC-FPD	15	調
73	エトキサゾール	ETOXAZOLE	—(*0.01	ND	0.05	GC-MSD	15	虫
74	エトフェンプロックス	ETOFENPROX	0.5	ND	0.01	GC-MSD	7	虫
75	エトフメセート	ETHOFUMESATE	—(*0.01	ND	0.01	GC-MSD	15	虫
76	エトプロホス	ETHOPROPHOS	0.02	ND	0.005	LC-MSMS	2	虫
77	エトベンザニド	ETOBENZANID	—(*0.01	ND	0.01	GC-ECD	15	草
78	エトリジアゾール	ETRIDIAZOLE	0.1	ND	0.05	GC-ECD	15	菌
79	エトリムホス	ETRIMFOS	—(*0.01	ND	0.01	GC-FPD	15	虫
80	エポキシコナゾール	EPOXICONAZOLE	—(*0.01	ND	0.01	GC-MSD	15	菌
81	エマメクチン安息香酸塩	EMAMECTIN BENZOATE	0.1	ND	0.01	LC-MSMS	15	虫
82	エンドスルファン	ENDOSULFAN	0.1	ND	0.01	GC-ECD	15	虫
83	エンドリン	ENDRIN	ND	ND	0.005	GC-ECD	0	虫
84	オキサジキシル	OXADIXYL	0.1	ND	0.1	LC-MSMS	15	菌
85	オキサジクロメホン	OXAZICLOMEFONE	0.02	ND	0.01	LC-MSMS	15	草
86	オキサミル	OXAMYL	0.05	ND	0.01	LC-MSMS	1	虫
87	オキシフルオルフェン	OXYFLUORFEN	0.05	ND	0.01	GC-MSD	15	草
88	オメトエート	OMETHOATE	2	ND	0.02	GC-FPD	15	虫
89	オリサストロビン	ORYSASTROBIN	—(*0.01	ND	0.01	GC-MSD	16	菌
90	オリザリン	ORYZALIN	0.01	ND	0.01	LC-MSMS	15	草
91	カフェンストロール	CAFFENSTROLE	—(*0.01	ND	0.01	LC-MSMS	15	草
92	カプタホール	CAPTAFOL	ND	ND	0.01	GC-ECD	7	菌
93	カルタップ、チオシクラム、及びベンスルタップ	CARTAP,THIOCYCLAM BENSULTAP	0.2	ND	0.05	LC-MSMS	15	虫
94	カルバリル	CARBARYL	0.1	ND	0.01	LC-MSMS	15	虫・調
95	カルフェントラゾンエチル	CARFENTRAZONE-ETHYL	0.08	ND	0.01	GC-ECD	15	草
96	カルプロパミド	CARPROPAMID	—(*0.01	ND	0.01	GC-MSD	28	菌
97	カルベンダジム、ベノミル、チオファネート及びチオファネートメチル	CARBENDAZIM, BENOMYL, THIOPHANATE, THIOPHANATE-METHYL	0.7	ND	0.02	LC-MSMS	15	菌
98	カルボキシン	CARBOXIN	0.2	ND	0.01	GC-MSD	15	菌
99	カルボスルファン	CARBOSULFAN	0.05	ND	0.01	GC-MSD	15	虫
100	カルボフラン	CARBOFURAN	0.05	ND	0.01	LC-MSMS	15	虫
101	キザロホップエチル	QUIZALOFOP-ETHYL	—(*0.01	ND	0.01	GC-MSD	15	草
102	キナルホス	QUINALPHOS	0.05	ND	0.01	GC-FPD	15	虫
103	キノキシフェン	QUINOXYFEN	—(*0.01	ND	0.01	GC-MSD	27	菌
104	キノクラミン	QUINOCLAMINE	—(*0.01	ND	0.01	LC-MSMS	15	菌
105	キノメチオナート	CHINOMETHONAT	0.1	ND	0.02	LC-MSMS	1	虫
106	キャプタン	CAPTAN	10	ND	0.01	GC-ECD	15	菌
107	キントゼン	QUINTOZENE	0.01	ND	0.01	GC-ECD	15	菌
108	クマホス	COUMAFOS/COUMAPHOS	ND	ND	0.01	GC-FPD	15	虫
109	クミルロン	CUMYLURON	—(*0.01	ND	0.02	LC-MSMS	28	草
110	グリホサート	GLYPHOSATE	1.0	0.04	0.02	GC-MSD	1	草
111	グルホシネート	GLUFOSINATE	0.10	ND	0.02	GC-MSD	2	草
112	クレソキシムメチル	KRESOXIM-METHYL	5	ND	0.01	GC-MSD	15	菌
113	クレトジム	CLETHODIM	1	ND	0.02	LC-MSMS	15	草
114	クロジナホッププロパルギル	CLODINAFOP-PROPARGYL	0.02	ND	0.01	LC-MSMS	15	草
115	クロジナホップ酸	CLODINAFOP ACID	—(*0.01	ND	0.05	LC-MSMS	15	草
116	クロゾリネート	CHLOZOLINATE	0.05	ND	0.05	GC-MSD	15	菌
117	クロチアニジン	CLOTHIANIDIN	0.02	ND	0.01	LC-MSMS	31	虫
118	クロピラリド	CLOPYRALID	2	ND	0.5	LC-MSMS	15	草
119	クロフェンテジン	CLOFENTEZINE	0.05	ND	0.01	LC-MSMS	11	虫
120	クロメプロップ	CLOMEPROP	—(*0.01	ND	0.02	LC-MSMS	15	草

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No.	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
121	クロルエトキシホス	CHLORETHOXYFOS	0.01	ND	0.01	GC-MSD	15	虫
122	クロルタールジメチル	CHLORTHAL-DIMETHYL	3	ND	0.04	GC-MSD	15	草
123	クロルデン	CHLORDANE	0.02	ND	0.01	GC-ECD	15	虫
124	クロルピリホス	CHLORPYRIFOS	0.1	ND	0.01	GC-FPD	1	虫
125	クロルピリホスメチル	CHLORPYRIFOS-METHYL	7	ND	0.01	GC-FPD	15	虫
126	クロルフェナピル	CHLORFENAPYR	一律0.01	ND	0.01	GC-ECD	30	虫
127	クロルフェンソン	CHLORFENSON	0.01	ND	0.01	GC-ECD	15	ダ
128	クロルフェンビンホス	CHLORFENVINPHOS	0.05	ND	0.01	GC-FPD	4・5	虫
129	クロルブファム	CHLORBUFAM	0.05	ND	0.01	GC-MSD	15	草
130	クロルフルアズロン	CHLORFLUAZURON	0.05	ND	0.01	LC-MSMS	15	虫
131	クロルプロファム	CHLORPROPHAM	0.05	ND	0.01	GC-MSD	1	草・調
132	クロルベンシド	CHLORBENSIDE	0.01	ND	0.01	GC-ECD	15	ダ
133	クロルメコート	CHLORMEQUAT	0.05	ND	0.02	LC-MSMS	15	調
134	クロロクスロン	CHLOROXURON	0.05	ND	0.05	LC-MSMS	15	草
135	クロロタロニル	CHLOROTHALONIL	0.01	ND	0.01	GC-ECD	13	菌
136	クロロネブ	CHLORONEB	一律0.01	ND	0.03	GC-ECD	15	菌
137	クロロベンジレート	CHLOROBENZILATE	0.02	ND	0.01	GC-MSD	15	ダ
138	シアナジン	CYANAZINE	0.1	ND	0.01	LC-MSMS	12	草
139	シアノホス	CYANOPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
140	ジアフェンチウロン	DIAFENTHIURON	0.02	ND	0.1	GC-MSD	15	虫
141	シアン化水素	HYDROGEN CYANIDE	20	ND	0.2	GC-NPD	15	虫
142	ジウロン	DIURON	0.7	ND	0.01	LC-MSMS	15	草
143	ジエトフェンカルブ	DIETHOFENCARB	一律0.01	ND	0.03	GC-MSD	15	菌
144	ジオキサチオン	DIOXATHION	0.05	ND	0.01	GC-FPD	15	虫
145	ジカンバ	DICAMBA	0.5	ND	0.02	LC-MSMS	8	草
146	シクラニリド	CYCLANILIDE	一律0.01	ND	0.01	LC-MSMS	15	調
147	シクロエート	CYCLOATE	一律0.01	ND	0.01	GC-MSD	15	草
148	ジクロシメット	DICLOCYMET	一律0.01	ND	0.01	GC-ECD	15	菌
149	ジクロスラム	DICLOSULAM	一律0.01	ND	0.02	LC-MSMS	15	草
150	シクロスルファムロン	CYCLOSULFAMURON	一律0.01	ND	0.01	LC-MSD	15	草
151	ジクロフェンチオン	DICHLOFENTHION	一律0.01	ND	0.01	GC-FPD	15	虫
152	ジクロフルアニド	DICHLOFLUANID	5	ND	0.05	GC-MSD	15	菌
153	シクロプロトリン	CYCLOPROTHRIN	0.02	ND	0.05	LC-MSMS	15	虫
154	ジクロベニル	DICHLOBENIL	0.05	ND	0.05	GC-MSD	15	草
155	ジクロホップメチル	DICLOFOP-METHYL	0.1	ND	0.01	GC-MSD	15	草
156	ジクロルプロップ	DICHLORPROP	0.05	ND	0.02	LC-MSMS	15	草・調
157	ジクロルボス、ナレド	DICHLORVOS, NALED	0.2	ND	0.01	GC-FPD	3	虫
158	ジクワット	DIQUAT	0.05	ND	0.02	LC-DAD	15	草
159	ジコホール	DICOFOL	3	ND	0.01	GC-MSD	15	虫
160	ジスルホトン	DISULFOTON	0.02	ND	0.01	GC-FPD	15	虫
161	ジチオピル	DITHIOPYR	一律0.01	ND	0.01	GC-ECD	15	草
162	シニドンエチル	CINIDON-ETHYL	0.1	ND	0.01	LC-MSMS	21	草
163	ジノカップ	DINOCAP	一律0.01	ND	0.01	LC-MSMS	15	虫
164	シハロトリン	CYHALOTHRIN	0.04	ND	0.01	GC-MSD	15	虫
165	シハロホップブチル	CYHALOFOP-BUTYL	一律0.01	ND	0.03	GC-MSD	15	草
166	ジフェノコナゾール	DIFENOCONAZOLE	0.1	ND	0.03	GC-MSD	7	菌
167	シフルトリン	CYFLUTHRIN	2.0	ND	0.03	GC-MSD	4・5	虫
168	シフルフェナミド	CYFLUFENAMID	1	ND	0.01	GC-MSD	15	菌
169	ジフルフェニカン	DIFLUFENICAN	0.1	ND	0.01	GC-MSD	15	草
170	ジフルベンズロン	DIFLUBENZURON	2	ND	0.01	LC-MSMS	15	虫
171	シプロコナゾール	CYPROCONAZOLE	0.1	ND	0.01	GC-MSD	8	菌
172	シプロジニル	CYPRODINIL	0.5	ND	0.01	LC-MSMS	12	菌
173	シペルメトリン	CYPERMETHRIN	0.2	ND	0.05	GC-MSD	1	虫
174	シマジン	SIMAZINE	0.3	ND	0.05	GC-MSD	15	草
175	シメコナゾール	SIMECONAZOLE	一律0.01	ND	0.01	LC-MSMS	15	菌
176	ジメタメトリン	DIMETHAMETRYN	一律0.01	ND	0.01	LC-MSMS	15	草
177	ジメチピン	DIMETHIPIN	0.04	ND	0.01	GC-ECD	15	草・調
178	ジメチリモール	DIMETHIRIMOL	一律0.01	ND	0.05	LC-MSMS	15	菌
179	ジメチルビンホス	DIMETHYLVINPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
180	ジメテナミド	DIMETHENAMID	0.1	ND	0.02	GC-ECD	9	草

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181	ジメトエート	DIMETHOATE	1	ND	0.01	GC-FPD	15	虫
182	ジメトモルフ	DIMETHOMORPH	一律0.01	ND	0.1	LC-MSMS	19	菌
183	シメトリン	SIMETRYN	一律0.01	ND	0.02	GC-MSD	15	草
184	ジメピペレート	DIMEPIPERATE	一律0.01	ND	0.01	GC-MSD	15	草
185	シモキサニル	CYMOXANIL	0.05	ND	0.02	LC-MSMS	15	菌
186	シロマジン	CYROMAZINE	0.3(一律0.01)	ND	0.05	LC-MSMS	32	虫
187	シンメチリン	CINMETHYLIN	一律0.01	ND	0.01	GC-MSD	15	草
188	スピノサド	SPINOSAD	0.02	ND	0.01	LC-MSMS	14	虫
189	スピロキサミン	SPIROXAMINE	一律0.01	ND	0.01	GC-MSD	15	虫
190	スピロジクロフェン	SPIRODICLOFEN	一律0.01	ND	0.01	LC-MSMS	15	虫
191	スルフェントラゾン	SULFENTRAZONE	0.2	ND	0.01	LC-MSMS	15	草
192	スルプロホス	SULPROFOS	一律0.01	ND	0.01	GC-FPD	15	虫
193	セトキシジム	SETHOXYDIM	0.2	ND	0.05	LC-MSMS	2	草
194	ターバシル	TERBACIL	一律0.01	ND	0.05	LC-MSMS	15	草
195	ダイアジノン	DIAZINON	0.02	ND	0.01	GC-FPD	15	虫
196	ダイアレート	DI-ALLATE	0.05	ND	0.02	GC-ECD	15	草
197	ダイムロン	DAIMURON	一律0.01	ND	0.01	LC-MSMS	15	草
198	ダゾメット、メタム及び メチルイソチオシアネート	DAZOMET, METHAM & METHYL-ISOTHIOCYANATE	一律0.01	ND	0.02	GC-MSD	15	虫
199	ダミノジット	DAMINOZIDE	ND	ND	0.1	GC-MSD	1	調
200	チアクロプリド	THIACLOPRID	一律0.01	ND	0.02	LC-MSMS	15	虫
201	チアジニル	TIADINIL	一律0.01	ND	0.01	LC-MSMS	15	菌
202	チアベンダゾール	THIABENDAZOLE	0.05	ND	0.05	LC-MSMS	15	菌
203	チアメトキサム	THIAMETHOXAM	0.02	ND	0.01	LC-MSMS	31	虫
204	チオジカルブ及びメソミル	THIODICARB, METHOMYL	0.02	ND	0.01	LC-MSMS	15	虫
205	チオベンカルブ	THIOBENCARB	0.03	ND	0.01	GC-MSD	30	草
206	チオメトン	THIOMETON	0.02	ND	0.01	GC-FPD	4・5	虫
207	チジアズロン	THIDIAZURON	一律0.01	ND	0.03	LC-MSMS	15	調
208	チフェンスルフロンメチル	THIFENSULFURON-METHYL	0.1	ND	0.01	LC-MSD	15	草
209	チフルザミド	THIFLUZAMIDE	一律0.01	ND	0.02	GC-ECD	15	菌
210	テクナゼン	TECNAZENE	0.05	ND	0.01	GC-ECD	15	菌・調
211	テトラクロルビンホス	TETRACHLORVINPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
212	テトラコナゾール	TETRACONAZOLE	一律0.01	ND	0.01	GC-MSD	15	菌
213	テトラジホン	TETRADIFON	5	ND	0.01	GC-ECD	15	ダ
214	テニルクロール	THENYLCHLOR	一律0.01	ND	0.01	GC-ECD	15	草
215	テブコナゾール	TEBUCONAZOLE	0.1	ND	0.03	GC-MSD	29	菌
216	テブフェノジド	TEBUFENOZIDE	5	ND	0.05	LC-MSMS	15	虫
217	テブフェンピラド	TEBUFENPYRAD	一律0.01	ND	0.01	GC-MSD	15	虫
218	テフルトリン	TEFLUTHRIN	0.1	ND	0.02	GC-MSD	7	虫
219	テフルベンズロン	TEFLUBENZURON	0.1	ND	0.02	LC-MSMS	9	虫
220	デメトン－S－メチル	DEMETON-S-METHYL	0.4	ND	0.01	GC-FPD	15	虫
221	デルタメトリン及びトラロメトリン	DELTAMETHRIN, TRALOMETHRIN	1.0	ND	0.03	GC-MSD	1	虫
222	テルブトリン	TERBUTRYN	0.1	ND	0.02	GC-MSD	15	草
223	テルブホス	TERBUFOS	0.01	ND	0.005	GC-FPD	3	虫
224	テレフタル酸銅	COPPER TELEPHTALATE	0.5	ND	0.3	LC-MSMS	15	菌
225	トラルコキシジム	TRALKOXYDIM	0.02	ND	0.01	LC-MSMS	15	草
226	トリアジメノール	TRIADIMENOL	0.1	ND	0.01	LC-MSMS	15	菌
227	トリアジメホン	TRIADIMEFON	0.1	ND	0.01	GC-MSD	15	菌
228	トリアスルフロン	TRIASULFURON	0.02	ND	0.01	LC-MSD	15	草
229	トリアゾホス	TRIAZOPHOS	ND	ND	0.01	GC-FPD	14	虫
230	トリアレート	TRI-ALLATE	0.05	ND	0.01	GC-ECD	15	草
231	トリクロピル	TRICLOPYR	0.03	ND	0.02	LC-MSMS	15	草
232	トリクロルホン	TRICHLORFON	0.10	ND	0.01	GC-FPD	1	虫
233	トリチコナゾール	TRITICONAZOLE	0.05	ND	0.01	LC-MSMS	15	菌
234	トリデモルフ	TRIDEMORPH	0.05	ND	0.01	LC-MSMS	15	菌
235	トリブホス	TRIBUPHOS	一律0.01	ND	0.01	GC-FPD	15	調
236	トリフルスルフロンメチル	TRIFLUSULFURON-METHYL	一律0.01	ND	0.01	LC-MSD	15	草
237	トリフルミゾール	TRIFLUMIZOLE	1.0	ND	0.01	GC-ECD	2	菌
238	トリフルムロン	TRIFLUMURON	0.05	ND	0.02	LC-MSMS	15	虫
239	トリフルラリン	TRIFLURALIN	0.05	ND	0.01	GC-ECD	9	草
240	トリフロキシストロビン	TRIFLOXYSTROBIN	0.05	ND	0.02	LC-MSMS	15	菌

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241	トリフロキシスルフロン	TRIFLOXYSULFURON	—(≥0.01	ND	0.01	LC-MSD	15	草
242	トリベヌロンメチル	TRIBENURON-METHYL	0.05	ND	0.05	LC-MSMS	15	草
243	トルクロホスメチル	TOLCLOFOS-METHYL	0.1	ND	0.01	GC-FPD	8	菌
244	ナプタラム	NAPTALAM	—(≥0.01	ND	0.05	LC-MSMS	15	草
245	ナプロアニリド	NAPROANILIDE	—(≥0.01	ND	0.01	GC-MSD	15	草
246	ナプロパミド	NAPROPAMIDE	—(≥0.01	ND	0.01	GC-MSD	15	草
247	ニコチン	NICOTINE	2	ND	0.02	GC-MSD	15	虫
248	ノバルロン	NOVALURON	—(≥0.01	ND	0.01	LC-MSMS	24	虫
249	ノルフルラゾン	NORFLURAZON	—(≥0.01	ND	0.03	GC-MSD	15	草
250	バミドチオン	VAMIDOTHION	0.2	ND	0.03	GC-FPD	11	虫
251	パラコート	PARAQUAT	0.1	ND	0.02	LC-DAD	15	草
252	パラチオン	PARATHION	0.3	ND	0.01	GC-FPD	0	虫
253	パラチオンメチル	PARATHION-METHYL	1.0	ND	0.01	GC-FPD	1	虫
254	ハロキシホップ	HALOXYFOP	—(≥0.01	ND	0.01	GC-MSD	15	草
255	ハロスルフロンメチル	HALOSULFURON METHYL	0.1(0.05)	ND	0.01	LC-MSD	33	草
256	ビオレスメトリン	BIORESMETHRIN	1	ND	0.05	GC-MSD	14	虫
257	ピコリナフェン	PICOLINAFEN	0.02	ND	0.01	LC-MSMS	15	草
258	ビテルタノール	BITERTANOL	0.05	ND	0.01	LC-MSMS	2	菌
259	ビフェナゼート	BIFENAZATE	—(≥0.01	ND	0.05	LC-MSMS	23	ダ
260	ビフェノックス	BIFENOX	—(≥0.01	ND	0.01	GC-ECD	15	草
261	ビフェントリン	BIFENTHRIN	0.05	ND	0.01	GC-MSD	21	虫
262	ピペロニルブトキシド	PIPERONYL BUTOXIDE	24	ND	0.02	GC-MSD	15	共
263	ピペロホス	PIPEROPHOS	—(≥0.01	ND	0.01	GC-FPD	15	草
264	ヒメキサゾール	HYMEXAZOL	0.02	ND	0.02	LC-MSMS	15	菌
265	ピメトロジン	PYMETROZINE	—(≥0.01	ND	0.01	LC-MSMS	15	虫
266	ピラクロストロビン	PYRACLOSTROBIN	0.1	ND	0.01	LC-MSMS	17	菌
267	ピラクロホス	PYRACLOFOS	—(≥0.01	ND	0.02	GC-FPD	15	虫
268	ピラゾキシフェン	PYRAZOXYFEN	—(≥0.01	ND	0.05	LC-MSMS	15	草
269	ピラゾホス	PYRAZOPHOS	0.05	ND	0.01	GC-FPD	15	菌
270	ピラゾリネート	PYRAZOLYNATE	0.02	ND	0.01	LC-MSMS	15	草
271	ピラフルフェンエチル	PYRAFLUFEN ETHYL	0.1(0.02)	ND	0.03	GC-MSD	33	草・調
272	ピリダフェンチオン	PYRIDAFENTHION	—(≥0.01	ND	0.01	GC-FPD	15	虫
273	ピリダベン	PYRIDABEN	—(≥0.01	ND	0.01	GC-ECD	15	虫
274	ピリダリル	PYRIDALYL	—(≥0.01	ND	0.01	LC-MSMS	28	虫
275	ピリフタリド	PYRIFTALID	—(≥0.01	ND	0.01	LC-MSMS	15	草
276	ピリブチカルブ	PYRIBUTICARB	—(≥0.01	ND	0.01	GC-MSD	15	草
277	ピリプロキシフェン	PYRIPROXYFEN	—(≥0.01	ND	0.01	GC-MSD	22	虫
278	ピリミカーブ	PIRIMICARB	0.05	ND	0.01	GC-MSD	1	虫
279	ピリミジフェン	PYRIMIDIFEN	—(≥0.01	ND	0.01	GC-MSD	15	虫
280	ピリミノバックメチル	PYRIMINOBAC-METHYL	—(≥0.01	ND	0.01	GC-MSD	15	草
281	ピリミホスメチル	PIRIMIPHOS-METHYL	1.0	ND	0.01	GC-FPD	4・5	虫
282	ピリメタニル	PYRIMETHANIL	—(≥0.01	ND	0.01	GC-MSD	15	菌
283	ピレトリン	PYRETHRIN	3	ND	0.1	GC-MSD	3	虫
284	ピロキロン	PYROQUILON	—(≥0.01	ND	0.01	GC-MSD	15	菌
285	ビンクロゾリン	VINCLOZOLIN	—(≥0.01	ND	0.01	GC-MSD	15	菌
286	ファモキサドン	FAMOXADONE	—(≥0.01	ND	0.02	LC-MSMS	15	菌
287	フィプロニル	FIPRONIL	0.02	ND	0.002	LC-MSMS	14	虫
288	フェナミホス	FENAMIPHOS	0.02	ND	0.01	GC-FPD	15	虫
289	フェナリモル	FENARIMOL	0.1	ND	0.01	GC-MSD	8	菌
290	フェニトロチオン	FENITROTHION	1.0	ND	0.01	GC-FPD	1	虫
291	フェノキサニル	FENOXANIL	—(≥0.01	ND	0.01	LC-MSMS	15	菌
292	フェノキサプロップエチル	FENOXAPROP-ETHYL	—(≥0.01	ND	0.01	GC-MSD	15	草
293	フェノチオカルブ	FENOTHIOCARB	—(≥0.01	ND	0.01	LC-MSMS	15	虫
294	フェノトリン	PHENOTHRIN	0.02	ND	0.02	GC-MSD	15	虫
295	フェノブカルブ	FENOBUCARB	0.3	ND	0.01	LC-MSMS	4・5	虫
296	フェリムゾン	FERIMZONE	—(≥0.01	ND	0.01	LC-MSMS	15	菌
297	フェンクロルホス	FENCHLORPHOS	0.01	ND	0.01	GC-FPD	15	虫
298	フェンスルホチオン	FENSULFOTHION	0.1	ND	0.01	GC-FPD	1	虫
299	フェンチオン	FENTHION	5	ND	0.01	GC-FPD	15	虫
300	フェンテン	FENTIN	0.05	ND	0.02	LC-MSMS	15	菌

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No.	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
301	フェントエート	PHENTHOATE	0.4	ND	0.01	GC-FPD	15	虫
302	フェントラザミド	FENTRAZAMIDE	一律0.01	ND	0.01	LC-MSMS	15	草
303	フェンバレレート	FENVALERATE	2.0	ND	0.05	GC-MSD	4・5	虫
304	フェンピロキシメート	FENPYROXIMATE	0.02	ND	0.02	LC-MSMS	15	虫
305	フェンブコナゾール	FENBUCONAZOLE	一律0.01	ND	0.02	LC-MSMS	15	菌
306	フェンプロパトリン	FENPROPATHRIN	一律0.01	ND	0.01	GC-MSD	15	虫
307	フェンプロピモルフ	FENPROPIMORPH	0.3	ND	0.01	GC-MSD	15	菌
308	ブタクロール	BUTACHLOR	一律0.01	ND	0.01	GC-MSD	15	草
309	ブタフェナシル	BUTAFENACIL	0.02	ND	0.01	GC-MSD	15	草
310	ブタミホス	BUTAMIFOS	一律0.01	ND	0.01	GC-FPD	15	草
311	ブチレート	BUTYLATE	0.1	ND	0.01	GC-MSD	9	草
312	ブピリメート	BUPIRIMATE	一律0.01	ND	0.01	GC-MSD	15	菌
313	ブプロフェジン	BUPROFEZIN	0.5	ND	0.01	GC-MSD	15	虫
314	フラチオカルブ	FURATHIOCARB	0.05	ND	0.01	LC-MSMS	15	虫
315	フラムプロップメチル	FLAMPROP-METHYL	一律0.01	ND	0.01	GC-MSD	15	草
316	フラメトピル	FURAMETPYR	0.1	ND	0.01	GC-MSD	15	菌
317	プリミスルフロンメチル	PRIMISULFURON-METHYL	0.05	ND	0.01	LC-MSD	15	草
318	フリラゾール	FURILAZOLE	0.01	ND	0.01	GC-ECD	15	殺
319	フルアジナム	FLUAZINAM	一律0.01	ND	0.05	LC-MSMS	15	虫・菌
320	フルアジホップ	FLUAZIFOP	一律0.01	ND	0.01	GC-MSD	15	草
321	フルオメツロン	FLUOMETURON	0.1	ND	0.02	LC-MSMS	15	草
322	フルキンコナゾール	FLUQUINCONAZOLE	一律0.01	ND	0.01	GC-MSD	15	菌
323	フルジオキソニル	FLUDIOXONIL	0.02	ND	0.01	LC-MSMS	9	菌
324	フルシトリネート	FLUCYTHRINATE	0.05	ND	0.02	GC-MSD	1	虫
325	フルシラゾール	FLUSILAZOLE	一律0.01	ND	0.01	GC-MSD	15	菌
326	フルチアセットメチル	FLUTHIACET-METHYL	0.1	ND	0.03	LC-MSMS	15	草
327	フルトラニル	FLUTOLANIL	一律0.01	ND	0.01	GC-MSD	15	菌
328	フルトリアホール	FLUTRIAFOL	0.02	ND	0.02	LC-MSMS	15	菌
329	フルバリネート	FLUVALINATE	一律0.01	ND	0.01	GC-MSD	15	虫
330	フルフェナセット	FLUFENACET	0.05	ND	0.01	GC-ECD	15	草
331	フルフェノクスロン	FLUFENOXURON	一律0.01	ND	0.01	LC-MSMS	20	虫
332	フルフェンピルエチル	FLUFENPYR-ETHYL	0.01	ND	0.01	LC-MSMS	15	草
333	フルミオキサジン	FLUMIOXAZIN	0.05	ND	0.03	LC-MSMS	15	草
334	フルミクロラックペンチル	FLUMICLORAC PENTYL	0.01	ND	0.02	LC-MSMS	15	草
335	フルリドン	FLURIDONE	0.1	ND	0.01	LC-MSMS	15	草
336	フルロキシピル	FLUROXYPYR	0.1	ND	0.01	LC-MSMS	15	草
337	プレチラクロール	PRETILACHLOR	一律0.01	ND	0.01	GC-MSD	15	草
338	プロクロラズ	PROCHLORAZ	2	ND	0.01	GC-MSD	15	菌
339	プロシミドン	PROCYMIDONE	0.02	ND	0.02	GC-MSD	15	菌
340	プロスルフロン	PROSULFURON	0.01	ND	0.01	LC-MSD	15	草
341	プロチオホス	PROTHIOFOS	一律0.01	ND	0.01	GC-FPD	15	虫
342	フロニカミド	FLONICAMID	一律0.01	ND	0.05	LC-MSMS	18	虫
343	プロパキザホップ	PROPAQUIZAFOP	一律0.01	ND	0.01	LC-MSMS	15	草
344	プロパクロール	PROPACHLOR	0.08	ND	0.01	GC-MSD	15	草
345	プロパジン	PROPAZINE	一律0.01	ND	0.01	GC-MSD	15	草
346	プロパニル	PROPANIL	一律0.01	ND	0.01	GC-MSD	15	草
347	プロパホス	PROPAPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
348	プロパルギット	PROPARGITE, BPPS	0.1	ND	0.01	GC-MSD	15	ダ
349	プロピコナゾール	PROPICONAZOLE	1.0	ND	0.03	GC-MSD	3	菌
350	プロピザミド	PROPYZAMIDE	0.02	ND	0.01	LC-MSMS	15	草
351	プロヒドロジャスモン	PROHYDROJASMON	一律0.01	ND	0.05	LC-MSMS	15	調
352	プロファム	PROPHAM	ND	ND	0.01	LC-MSMS	15	草・調
353	プロフェノホス	PROFENOFOS	0.05	ND	0.01	GC-FPD	15	虫
354	プロヘキサジオンカルシウム塩	PROHEXADIONE CALCIUM	0.2	ND	0.1	LC-MSMS	7	調
355	プロポキシカルバゾン	PROPOXYCARBAZONE	一律0.01	ND	0.01	LC-MSMS	15	草
356	プロポキスル(プロポクスル)	PROPOXUR	0.5	ND	0.01	LC-MSMS	15	虫
357	ブロマシル	BROMACIL	一律0.01	ND	0.02	LC-MSMS	15	草
358	ブロメトリン	PROMETRYN	0.2	ND	0.02	GC-MSD	15	草
359	ブロモキシニル	BROMOXYNIL	0.2	ND	0.05	LC-MSMS	15	草
360	ブロモブチド	BROMOBUTIDE	一律0.01	ND	0.01	GC-MSD	15	草

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361	ブロモプロピレート	BROMOPROPYLATE	0.05	ND	0.01	GC-MSD	15	ダ
362	ブロモホスエチル	BROMOPHOS-ETHYL	0.05	ND	0.01	GC-FPD	15	虫
363	ヘキサクロロベンゼン	HEXACHLOROBENZENE	0.03	ND	0.01	GC-ECD	15	菌
364	ヘキサコナゾール	HEXACONAZOLE	0.02	ND	0.01	LC-MSMS	15	菌
365	ヘキサジノン	HEXAZINONE	一律0.01	ND	0.01	GC-MSD	15	草
366	ヘキサフルムロン	HEXAFLUMURON	0.02	ND	0.01	LC-MSMS	15	虫
367	ヘキシチアゾクス	HEXYTHIAZOX	0.05	ND	0.02	LC-MSMS	15	虫
368	ベナラキシル	BENALAXYL	0.05	ND	0.01	GC-MSD	15	菌
369	ベノキサコール	BENOXACOR	0.01	ND	0.01	GC-ECD	15	軽
370	ベノキススラム	PENOXSULAM	一律0.01	ND	0.01	LC-MSD	21	草
371	ヘプタクロル	HEPTACHLOR	0.02	ND	0.01	GC-ECD	15	虫
372	ペルメトリン	PERMETHRIN	2.0	ND	0.02	GC-MSD	1	虫
373	ペンコナゾール	PENCONAZOLE	0.05	ND	0.01	GC-MSD	15	菌
374	ペンシクロン	PENCYCURON	0.1	ND	0.01	LC-MSMS	15	菌
375	ペンスリド	BENSULIDE	0.03	ND	0.02	LC-MSMS	15	草
376	ベンスルフロンメチル	BENSULFURON-METHYL	0.02	ND	0.01	LC-MSD	15	草
377	ベンゾビシクロン	BENZOBICYCLON	一律0.01	ND	0.02	LC-MSMS	15	草
378	ベンゾフェナップ	BENZOFENAP	一律0.01	ND	0.01	LC-MSMS	15	草
379	ベンダイオカルブ	BENDIOCARB	0.05	ND	0.01	LC-MSMS	1	虫
380	ベンタゾン	BENTAZONE	0.2	ND	0.02	LC-MSMS	3	草
381	ペンディメタリン	PENDIMETHALIN	0.2	ND	0.02	GC-MSD	2	草・調
382	ペントキサゾン	PENTOXAZONE	一律0.01	ND	0.01	GC-ECD	15	草
383	ベンフラカルブ	BENFFURACARB	0.05	ND	0.01	LC-MSMS	15	虫
384	ベンフレセート	BENFURESATE	一律0.01	ND	0.01	GC-MSD	15	草
385	ホキシム	PHOXIM	0.05	ND	0.02	LC-MSMS	4・5	虫
386	ホサロン	PHOSALONE	一律0.01	ND	0.01	GC-FPD	15	虫
387	ボスカリド	BOSCALID	一律0.01	ND	0.01	GC-ECD	15	菌
388	ホスチアゼート	FOSTHIAZATE	一律0.01	ND	0.01	GC-FPD	15	虫
389	ホスファミドン	PHOSPHAMIDON	0.1	ND	0.01	GC-FPD	15	虫
390	ホスメット	PHOSMET	0.05	ND	0.01	GC-FPD	15	虫
391	ホメサフェン	FOMESAFEN	一律0.01	ND	0.03	LC-MSMS	15	草
392	ホラムスルフロン	FORAMSULFURON	0.01	ND	0.01	LC-MSD	15	草
393	ホルモチオン	FORMOTHION	0.02	ND	0.02	GC-FPD	15	虫
394	ホレート	PHORATE	0.05	ND	0.01	GC-FPD	15	虫
395	マラチオン	MALATHION	2.0	ND	0.01	GC-FPD	1	虫
396	マレイン酸ヒドラジド	MALEIC HYDRAZIDE	1	ND	0.2	LC-DAD	16	草・調
397	ミクロブタニル	MYCLOBUTANIL	0.03	ND	0.01	GC-MSD	15	菌
398	ミルベメクチン	MILBEMECTIN	0.02	ND	0.05	LC-MSMS	15	ダ
399	メカルバム	MECARBAM	0.05	ND	0.01	GC-FPD	15	虫
400	メコプロップ	MECOPROP	0.05	ND	0.01	LC-MSMS	15	草
401	メソスルフロンメチル	MESOSULFURON-METHYL	一律0.01	ND	0.01	LC-MSD	15	草
402	メタクリホス	METHACRIFOS	0.05	ND	0.01	GC-FPD	15	虫
403	メタベンズチアズロン	METHABENZTHIAZURON	0.1	ND	0.01	GC-MSD	9	草
404	メタミドホス	METHAMIDOPHOS	0.1	ND	0.01	LC-MSMS	15	虫
405	メタラキシル及びメフェノキサム	METALAXYL, MEFENOXAM	0.05	ND	0.01	GC-MSD	15	菌
406	メチオカルブ	METHIOCARB	0.05	ND	0.01	LC-MSMS	4・5	虫
407	メチダチオン	METHIDATHION	0.1	ND	0.01	LC-MSMS	15	虫
408	メトキシクロール	METHOXYCHLOR	7	ND	0.01	GC-ECD	15	虫
409	メトキシフェノジド	METHOXYFENOZIDE	0.02	ND	0.01	LC-MSMS	29	虫
410	メトコナゾール	METCONAZOLE	一律0.01	ND	0.02	GC-MSD	29	菌
411	メトスラム	METOSULAM	0.02	ND	0.01	LC-MSMS	15	草
412	メトプレン	METHOPRENE	5.0	ND	0.01	GC-MSD	1	虫
413	メトミノストロビン	METOMINOSTROBIN	一律0.01	ND	0.01	GC-MSD	15	菌
414	メトラクロール	METOLACHLOR	0.1	ND	0.01	GC-MSD	8	草
415	メトリブジン	METRIBUZIN	0.1	ND	0.01	GC-MSD	2	草
416	メピコートクロリド	MEPIQUAT CHLORIDE	2	ND	0.02	LC-MSMS	15	調
417	メビンホス	MEVINPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
418	メフェナセット	MEFENACET	一律0.01	ND	0.01	LC-MSMS	15	草
419	メフェンピルジエチル	MEFENPYR-DIETHYL	0.01	ND	0.01	LC-MSMS	15	軽
420	メプロニル	MEPRONIL	一律0.01	ND	0.01	GC-MSD	15	菌

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421	モノクロトホス	MONOCROTOPHOS	一律0.01	ND	0.01	GC-FPD	15	虫
422	モノリニュロン	MONOLINURON	0.05	ND	0.01	LC-MSMS	15	草
423	モリネート	MOLINATE	0.02	ND	0.01	GC-MSD	15	草
424	ラクトフェン	LACTOFEN	一律0.01	ND	0.02	LC-MSMS	15	草
425	リニュロン	LINURON	0.2	ND	0.02	LC-MSMS	15	草
426	リン化水素	HYDROGEN PHOSPHIDE	0.1	ND	0.02	GC-FPD	15	く・虫
427	ルフェヌロン	LUFENURON	0.05	ND	0.01	LC-MSMS	12	虫
428	レスメトリン	RESMETHRIN	0.1	ND	0.01	GC-MSD	15	虫
429	レナシル	LENACIL	一律0.01	ND	0.05	LC-MSMS	15	草
430	酸化フェンブタスズ	FENBUTATIN OXIDE	0.05	ND	0.02	LC-MSMS	15	虫
431	酸化プロピレン	PROPYLENE OXIDE	一律0.01	ND	0.005	GC-MSD	15	く
432	臭素	BROMIDE (INORGANIC BROMIDE)	80	2.5	1	GC-AED	1	く・虫
433	二臭化エチレン	ETHYLENE DIBROMIDE	0.01	ND	0.005	GC-MSD	15	虫

ND: 検出せず

<告示・告示日・施行日一覧>

告示0	従来から基準のあったもの	5	項目
告示1	平成 4年 10月 27日告示分 (平成 5年 8月 1日施行)	21	項目
告示2	平成 5年 3月 4日告示分 (平成 5年 8月 1日施行)	7	項目
告示3	平成 5年 9月 14日告示分 (平成 6年 4月 1日施行)	7	項目
告示4・5	平成 6年 6月 6日告示分 (平成 7年 1月 1日施行)	12	項目
告示6	平成 7年 8月 14日告示分 (平成 8年 3月 1日施行)	3	項目
告示7	平成 8年 3月 2日告示分 (平成 9年 3月 1日施行)	5	項目
告示8	平成 9年 8月 1日告示分 (平成 10年 3月 1日施行)	7	項目
告示9	平成10年 10月 12日告示分 (平成 11年 4月 1日施行)	6	項目
告示10	平成11年 11月 22日告示分 (平成 12年 4月 1日施行)	1	項目
告示11	平成12年 12月 4日告示分 (平成 13年12月4日施行)	2	項目
告示12	平成13年 2月 26日告示分 (平成 13年 4月1日施行)	4	項目
告示13	平成13年 7月 24日告示分 (平成 13年10月1日施行)	1	項目
告示14	平成14年 3月 13日告示分 (平成 14年 4月1日施行)	4	項目
告示15	平成17年 11月 29日告示分(平成18年 5月29日施行)	319	項目
告示16	平成18年7月11日告示分(平成18年8月11日施行)	1	項目
告示17	平成18年8月25日告示分(平成18年9月25日施行)	1	項目
告示18	平成18年10月6日告示分(平成18年10月6日施行)	1	項目
告示19	平成19年10月 26日告示分(平成19年10月26日施行)	1	項目
告示20	平成19年10月 26日告示分(平成20年4月26日施行)	1	項目
告示21	平成19年12月 28日告示分(平成19年12月28日施行)	3	項目
告示22	平成19年12月 28日告示分(平成20年6月28日施行)	1	項目
告示23	平成19年4月 26日告示分(平成19年10月26日施行)	1	項目
告示24	平成19年5月 31日告示分(平成19年12月1日施行)	1	項目
告示25	平成19年5月 31日告示分(平成19年5月31日施行)	0	項目
告示26	平成19年8月 21日告示分(平成20年2月21日施行)	1	項目
告示27	平成20年1月24日告示分(平成20年1月24日施行)	1	項目
告示28	平成20年6月 30日告示分(平成20年12月30日施行)	2	項目
告示29	平成20年6月 30日告示分(平成20年6月30日施行)	4	項目
告示30	平成20年11月27日告示分(平成21年5月27日施行)	2	項目
告示31	平成21年7月2日告示分(平成21年7月2日施行)	2	項目
告示32	平成21年5月8日告示分(平成21年11月8日施行予定)	2	項目
告示33	平成21年6月4日告示分(平成21年12月4日施行予定)	4	項目

号 (草)除草剤 (殺)殺菌剤 (虫)殺虫剤 (調)植物調整剤 (くん)燻蒸剤 (線)線虫剤 (共)共力剤 (ダ)殺ダニ剤
出典(農薬便覧第10版等 2004年6月15日発行 他)

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OMIC USA Inc.

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Registered ISO 9001 : 2000 Laboratory

ORIGINAL

DATE: August 15, 2007.
No. JF54Z00222-2A

CERTIFICATE OF ANALYSIS (分析証明書)

APPLICANT(申請者):	Japan Starch & Sweetners Industry Association/Japan Corn Grits Association (日本スターチ・糖化工業会/社団法人 日本コーングリッツ協会)
SAMPLE DESCRIPTION(サンプル):	US Maize 2006 Crop (平成18年産アメリカ産トウモロコシ)
SAMPLE SUBMITTED(サンプル提供者):	MITSUI & CO., LTD. (三井物産株式会社)
PLACE OF SAMPLING (サンプル採取場所):	MINNESOTA WINNONA RIVER TERMINAL
SAMPLED BY(サンプル採取者):	MARK. SACKMASTER
DATE OF SAMPLING (サンプル採取日):	July 23, 2007. (平成19年7月23日)
CONDITION OF SAMPLE(サンプルの状態):	Cloth Bag (布製バッグ入り)
SAMPLE DATE RECEIVED(受領日):	August 2, 2007. (平成19年8月2日)

****

THIS IS TO CERTIFY that we, OMIC USA Inc., Portland, Oregon did carry out agricultural chemical residue analysis on the submitted sample with the above-mentioned details.
(OMIC USA Inc. で実施した上述の提出サンプルの分析について次のとおり証明する)

PLACE AND DATE OF ANALYSIS (分析所及び分析日)

At the laboratory of OMIC USA Inc., Portland, Oregon between August 2 and August 15, 2007.
(分析場所：アメリカ合衆国オレゴン州ポートランド市在 OMIC USA Inc. 分析期間：平成19年8月2日～8月16日)
OMIC USA Inc.は日本国厚生労働省の輸出国公的検査機関リストに指定検査機関(Registered laboratory)として登録されております。
(http://www.mhlw.go.jp/topics/yunyu/5/index.htmlをご参照ください。)

RESULTS (分析結果)

The contents of the required agricultural chemical residues and components are not detected and found as per the attached ANALYSIS RESULTS. (依頼を受けた農薬の検査結果は別紙のとおり)

This certificate refers to our intervention and findings at the time and place mentioned above only.

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OMIC USA Inc.

President

Checked by a

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Registered ISO 9001 : 2000 Laboratory

分析検査結果一覧表(米国とうもろこし・使用されている主な農薬69項目)

No.	Test Name(分析項目)		Japan 食品衛生法	LOQ 定量限界値	Result 検査結果	Instrument 分析方法	出荷	系
1	2,4-D	2,4-D	0.05	0.02	ND	LC-MSMS	10	除
2	アセトクロール	Acetochlor	0.05	0.01	ND	GC-ECD	15	草
3	アラクロール	Alachlor	0.2	0.01	ND	GC-ECD	9	草
4	アメトリン	Ametryn	0.3	0.01	ND	LC-MSMS	15	草
5	アトラジン	Atrazine	0.2	0.01	ND	GC-MSD	15	草
6	ベンタゾン	Bentazone	0.2	0.02	ND	LC-MSMS	3	草
7	ビフェントリン	Bifenthrin	0.05	0.01	ND	GC-MSD	9	虫
8	臭素	Bromide (Inorganic Bromide)	80	1	ND	GC-AED	1	く
9	ブロモキシニル	Bromoxynil	0.2	0.05	ND	LC-MSMS	15	草
10	ブチレート	Butylate	0.1	0.01	ND	GC-MSD	9	草
11	キャプタン	Captan	10	0.01	ND	GC-ECD	15	菌
12	カルボフラン	Carbofuran	0.05	0.01	ND	LC-MSD	15	虫
13	カルフェントラゾンエチル	Carfentrazone-Ethyl	0.05	0.01	ND	GC-MSD	15	草
14	クロルポトキシホス	Chlorethoxyfos	0.01	0.01	ND	GC-AED	15	虫
15	クロルピリホス	Chlorpyrifos	0.1	0.01	ND	GC-FPD	1	虫
16	クロピラリド	Clopyralid	2	0.5	ND	LC-MSMS	15	草
17	シアナジン	Cyanazine	0.1	0.01	ND	LC-MSMS	12	草
18	シフルトリン	Cyfluthrin	2.00	0.03	ND	GC-MSD	4・5	虫
19	シハロトリン	Cyhalothrin	0.04	0.01	ND	GC-MSD	15	虫
20	シペルメトリン	Cypermethrin	0.2	0.05	ND	GC-MSD	1	虫
21	ダイアジノン	Diazinon	0.02	0.01	ND	GC-FPD	15	虫
22	ジカンバ	Dicamba	0.5	0.02	ND	LC-MSMS	6	草
23	ジクロルプロップ	Dichlorprop	0.05	0.02	ND	LC-MSMS	15	草
24	ジフルフェンゾピル	Diflufenzopyr	0.05	0.01	ND	LC-MSMS	15	草
25	ジメテナミド	Dimethenamid	0.1	0.02	ND	GC-ECD	9	草
26	ジメトエート	Dimethoate	1	0.01	ND	GC-FPD	15	虫
27	EPTC	EPTC	0.1	0.01	ND	GC-MSD	6	草
28	フェニトロチオン	Fenitrothion	1	0.01	ND	GC-FPD	1	虫
29	フェンバレレート	Fenvalerate	2	0.05	ND	GC-MSD	4・6	虫
30	フィプロニル	Fipronil	0.02	0.002	ND	LC-MSMS	14	虫
31	フルフェナセット	Flufenacet	0.05	0.01	ND	GC-AED	15	草
32	フルメツラム	Flumetsulam	0.05	0.02	ND	LC-MSMS	15	草
33	ホノホス	Fonofos	一律0.01	0.01	ND	GC-FPD	*	虫
34	ホラムスルフロン	Foramsulfuron	0.01	0.01	ND	LC-MSD	15	草
35	グルホシネート	Glufosinate	0.1	0.02	ND	GC-MSD	2	草
36	グリホサート	Glyphosate	1	0.02	ND	GC-MSD	1	草
37	ハロスルフロンメチル	Halosulfuron Methyl	0.1	0.01	ND	LC-MSD	14	草
38	リン化水素	Hydrogen Phosphide	0.1	0.02	ND	GC-FPD	15	く
39	イマザピル	Imazapyr	0.05	0.02	ND	LC-MSMS	15	草・菌
40	イマゼタピルアンモニウム塩	Imazethapyr Ammonium	0.05	0.02	ND	LC-MSMS	15	草
41	イオドスルフロンメチル	Iodosulfuron Methyl	0.03	0.01	ND	LC-MSD	15	草
42	イソキサフルトール	Isoxaflutole	0.1	0.01	ND	LC-MSMS	15	草
43	リニュロン	Linuron	0.2	0.02	ND	LC-MSMS	15	草
44	マラチオン	Malathion	2	0.01	ND	GC-FPD	1	虫
45	MCPA	Mcpa	0.1	0.03	ND	LC-MSMS	8	草・菌
46	メソトリオン	Mesotrione	0.01	0.01	ND	LC-MSD	16	草
47	メタラキシル&Dメフェノキサム	Metalaxyl, Mefenoxam	0.05	0.01	ND	GC-MSD	15	菌
48	メトラクロール	Metolachlor	0.1	0.01	ND	GC-MSD	8	草
49	メトリブジン	Metribuzin	0.1	0.01	ND	GC-MSD	2	草
50	ニコスルフロン	Nicosulfuron	0.1	0.01	ND	LC-MSD	16	草
51	パラコート	Paraquat	0.1	0.02	ND	LC-DAD	15	除
52	パラチオンメチル	Parathion-Methyl	1.0	0.01	ND	GC-FPD	1	虫
53	ペンディメタリン	Pendimethalin	0.2	0.02	ND	GC-MSD	2	草・菌
54	ペルメトリン	Permethrin	2	0.02	ND	GC-MSD	1	虫
55	ホレート	Phorate	0.05	0.01	ND	GC-FPD	15	虫
56	ピリミホスメチル	Pirimiphos-Methyl	1	0.01	ND	GC-FPD	4・5	虫

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Registered Lab of MHLW, Japan / KFDA, Korea
Registered ISO 9001 : 2000 Laboratory

No.	Test Name (分析項目)		Japan 食品用基準	LOQ 定量限界値	Result 検査結果	Instrument 分析方法	告示	区
57	プリミスルフロンメチル	Primisulfuron-Methyl	0.06	0.01	ND	LC-MSD	15	除
58	プロパクロール	Propachlor	0.08	0.01	ND	GC-MSD	15	除
59	プロパルギット	Propargite, Ippa	0.1	0.01	ND	GC-MSD	15	殺
60	プロスルフロン	Prosulfuron	0.01	0.01	ND	LC-MSD	15	除
61	ピリデート	Pyridate	0.03	0.02	ND	LC-MSMS	7	除
62	リムスルフロン	Rimsulfuron	0.1	0.01	ND	LC-MSD	15	除
63	シマジン	Simazine	0.3	0.05	ND	GC-MSD	15	除
64	テブピリムホス	Tebupirimphos	一律0.01	0.02	ND	GC-AED	*	殺
65	テフルトリン	Tefluthrin	0.1	0.02	ND	GC-MSD	7	殺
66	テルブホス	Terbufos	0.01	0.005	ND	GC-FPD	3	殺
67	チフェンスルフロン	Thifensulfuron	0.1	0.01	ND	LC-MSD	15	除
68	トリフルラリン	Trifluralin	0.05	0.01	ND	GC-ECD	9	除
69	ベルノレート	Vernolate	一律0.01	0.01	ND	LC-MSMS	*	除

ND: 検出せず

<告示・告示日・施行日一覧>

告示	1	平成 4年 10月 27日告示分 (平成 5年 5月 1日施行)	8	項目
告示	2	平成 5年 3月 4日告示分 (平成 5年 9月 1日施行)	3	項目
告示	3	平成 3年 8月 14日告示分 (平成 4年 4月 1日施行)	2	項目
告示	4・5	平成 6年 9月 8日告示分 (平成 7年 1月 1日施行)	3	項目
告示	7	平成 8年 9月 2日告示分 (平成 9年 3月 1日施行)	2	項目
告示	8	平成 9年 8月 1日告示分 (平成 10年 3月 1日施行)	5	項目
告示	9	平成10年 10月 12日告示分 (平成 11年 4月 1日施行)	4	項目
告示	10	平成11年 11月 22日告示分 (平成 12年 4月 1日施行)	1	項目
告示	12	平成13年 2月 28日告示分 (平成 13年 4月 1日施行)	1	項目
告示	14	平成14年 3月 13日告示分 (平成 14年 4月 1日施行)	2	項目
告示	15	平成17年 11月 29日告示分 (平成 18年 5月 29日施行)	15	項目
*		食品衛生法に記載のない物質	3	項目

凡例 (殺)殺虫剤 (除)除草剤 (菌)殺菌剤 (植)植物調整剤 (その)その他
出典(農薬便覧第10版 2004年8月15日発行)

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Accredited ISO/IEC 17025:2005

ORIGINAL

DATE: July 2, 2009
No. JF56Z00155A

CERTIFICATE OF ANALYSIS (分析証明書)

APPLICANT(申請者):	Japan Starch & Sweetners Industry Association/Japan Corn Grits Association (日本スターチ・糖化工業会/社団法人 日本コーングリッツ協会)
SAMPLE DESCRIPTION(サンプル):	US Maize 2008 Crop (2008年産アメリカ産トウモロコシ)
PLACE OF SAMPLING (サンプル採取場所):	HENNEPIN, IL, USA(アメリカ合衆国、イリノイ州、ヘネピン)
SAMPLED BY(サンプル採取者):	CGB
DATE OF SAMPLING (サンプル採取日):	June 11, 2009 (2009年6月11日)
CONDITION OF SAMPLE(サンプルの状態):	Plastic Bag (プラスチックバッグ入り)
SAMPLE DATE RECEIVED(受領日):	June 22, 2009 (2009年6月22日)

****

THIS IS TO CERTIFY that we, OMIC USA Inc., Portland, Oregon did carry out agricultural chemical residue analysis on the submitted sample with the above-mentioned details.
(OMIC USA Inc. で実施した上述の提出サンプルの分析について次のとおり証明する)

PLACE AND DATE OF ANALYSIS (分析所及び分析日)

At the laboratory of OMIC USA Inc., Portland, Oregon between June 23, 2009 and July 2, 2009.
(分析場所：アメリカ合衆国オレゴン州ポートランド市在 OMIC USA Inc. 分析期間：2009年6月23日～2009年7月2日)
OMIC USA Inc.は日本国厚生労働省の輸出国公的検査機関リストに指定検査機関(Registered laboratory)として登載されております。
(http://www.mhlw.go.jp/topics/yunyu/5/index.htmlをご参照ください。)

RESULTS (分析結果)

The contents of the required agricultural chemical residues and components are not detected and found as per the attached ANALYSIS RESULTS. (依頼を受けた農薬の検出結果は別紙のとおり)

This certificate refers to our intervention and findings at the time and place mentioned above only.

OMIC USA Inc.

President

Checked by K.Y

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Accredited ISO/IEC 17025:2005

分析検査結果一覧表（米国とうもろこし・使用されている主な農薬69項目）

No.	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
1	2,4-D	2,4-D	0.05	ND	0.02	LC-MSMS	10	草
2	アセトクロール	Acetochlor	0.05	ND	0.01	GC-ECD	15	草
3	アラクロール	Alachlor	0.2	ND	0.01	GC-ECD	9	草
4	アメトリン	Ametryn	0.3(0.05)	ND	0.01	LC-MSMS	33	草
5	アトラジン	Atrazine	0.2	ND	0.01	GC-MSD	15	草
6	ベンタゾン	Bentazone	0.2	ND	0.02	LC-MSMS	3	草
7	ビフェントリン	Bifenthrin	0.05	ND	0.01	GC-MSD	21	虫
8	臭素	Bromide (Inorganic Bromide)	80	2.5	1	GC-AED	1	く・虫
9	ブロモキシニル	Bromoxynil	0.2	ND	0.05	LC-MSMS	15	草
10	ブチレート	Butylate	0.1	ND	0.01	GC-MSD	8	草
11	キャプタン	Captan	10	ND	0.01	GC-ECD	15	菌
12	カルボフラン	Carbofuran	0.05	ND	0.01	LC-MSMS	15	虫
13	カルフェントラゾンエチル	Carfentrazone-Ethyl	0.08	ND	0.01	GC-ECD	15	草
14	クロルエトキシホス	Chlorethoxyfos	0.01	ND	0.01	GC-MSD	15	虫
15	クロルピリホス	Chlorpyrifos	0.1	ND	0.01	GC-FPD	1	虫
16	クロピラリド	Clopyralid	2	ND	0.5	LC-MSMS	15	草
17	シアナジン	Cyanazine	0.1	ND	0.01	LC-MSMS	12	草
18	シフルトリン	Cyfluthrin	2.0	ND	0.03	GC-MSD	4・5	虫
19	シハロトリン	Cyhalothrin	0.04	ND	0.01	GC-MSD	15	虫
20	シペルメトリン	Cypermethrin	0.2	ND	0.05	GC-MSD	1	虫
21	ダイアジノン	Diazinon	0.02	ND	0.01	GC-FPD	15	虫
22	ジカンバ	Dicamba	0.5	ND	0.02	LC-MSMS	8	草
23	ジクロルプロップ	Dichlorprop	0.05	ND	0.02	LC-MSMS	15	草・調
24	ジフルフェンゾピル	Diflufenzopyr	0.05	ND	0.01	LC-MSMS	15	草
25	ジメテナミド	Dimethenamid	0.1	ND	0.02	GC-ECD	9	草
26	ジメトエート	Dimethoate	1	ND	0.01	GC-FPD	15	虫
27	EPTC	EPTC	0.1	ND	0.01	GC-MSD	8	草
28	フェニトロチオン	Fenitrothion	1.0	ND	0.01	GC-FPD	1	虫
29	フェンバレレート	Fenvalerate	2.0	ND	0.05	GC-MSD	4・5	虫
30	フィプロニル	Fipronil	0.02	ND	0.002	LC-MSMS	14	虫
31	フルフェナセット	Flufenacet	0.05	ND	0.01	GC-ECD	15	草
32	フルメツラム	Flumetsulam	0.05	ND	0.02	LC-MSMS	15	草
33	ホノホス	Fonofos	—/#0.01	ND	0.01	GC-FPD	*	虫
34	ホラムスルフロン	Foramsulfuron	0.01	ND	0.01	LC-MSD	15	草
35	グルホシネート	Glufosinate	0.10	ND	0.02	GC-MSD	2	草
36	グリホサート	Glyphosate	1.0	0.04	0.02	GC-MSD	1	草
37	ハロスルフロンメチル	Halosulfuron Methyl	0.1(0.05)	ND	0.01	LC-MSD	33	草
38	リン化水素	Hydrogen Phosphide	0.1	ND	0.02	GC-FPD	15	く・虫
39	イマザピル	Imazapyr	0.05	ND	0.02	LC-MSMS	15	草・調
40	イマゼタピルアンモニウム塩	Imazethapyr Ammonium	0.08	ND	0.02	LC-MSMS	15	草
41	イオドスルフロンメチル	Iodosulfuron Methyl	0.03	ND	0.01	LC-MSD	15	草
42	イソキサフルトール	Isoxaflutole	0.1	ND	0.01	LC-MSMS	15	草
43	リニュロン	Linuron	0.2	ND	0.02	LC-MSMS	15	草
44	マラチオン	Malathion	2.0	ND	0.01	GC-FPD	1	虫
45	MCPA	Mcpa	0.1	ND	0.03	LC-MSMS	8	草・調
46	メソトリオン	Mesotrione	0.01	ND	0.01	LC-MSMS	15	草
47	メタラキシル及びメフェノキサム	Metalaxyl, Mefenoxam	0.05	ND	0.01	GC-MSD	15	菌
48	メトラクロール	Metolachlor	0.1	ND	0.01	GC-MSD	8	草
49	メトリブジン	Metribuzin	0.1	ND	0.01	GC-MSD	2	草
50	ニコスルフロン	Nicosulfuron	0.1	ND	0.01	LC-MSD	15	草
51	パラコート	Paraquat	0.1	ND	0.02	LC-DAD	15	草
52	パラチオンメチル	Parathion-Methyl	1.0	ND	0.01	GC-FPD	1	虫
53	ペンディメタリン	Pendimethalin	0.2	ND	0.02	GC-MSD	2	草・調
54	ペルメトリン	Permethrin	2.0	ND	0.02	GC-MSD	1	虫
55	ホレート	Phorate	0.05	ND	0.01	GC-FPD	15	虫
56	ピリミホスメチル	Pirimiphos-Methyl	1.0	ND	0.01	GC-FPD	4・5	虫
57	プリミスルフロンメチル	Primisulfuron Methyl	0.06	ND	0.01	LC-MSD	15	草
58	プロパクロール	Propachlor	0.08	ND	0.01	GC-MSD	15	草
59	プロパルギット	Propargite Bpps	0.1	ND	0.01	GC-MSD	15	ダ
60	プロスルフロン	Prosulfuron	0.01	ND	0.01	LC-MSD	15	草

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Registered Lab of MHLW, Japan / KFDA, Korea
Accredited ISO/IEC 17025:2005

No.	分析項目	Items	Japan 食品用基準 (ppm)	Result 検査結果 (ppm)	LOQ 定量限界値 (ppm)	Instrument 分析方法	告示	系
61	ピリデート	Pyridate	0.03	ND	0.02	LC-MSMS	7	草
62	リムスルフロン	Rimsulfuron	0.1	ND	0.01	LC-MSD	15	草
63	シマジン	Simazine	0.3	ND	0.05	GC-MSD	15	草
64	テブピリムホス	Tebupirimphos	一律0.01	ND	0.02	GC-FPD	*	虫
65	テフルトリン	Tefluthrin	0.1	ND	0.02	GC-MSD	7	虫
66	テルブホス	Terbufos	0.01	ND	0.005	GC-FPD	3	虫
67	チフェンスルフロン	Thifensulfuron	0.1	ND	0.01	LC-MSD	15	草
68	トリフルラリン	Trifluralin	0.05	ND	0.01	GC-ECD	9	草
69	バルノレート	Vernolate	一律0.01	ND	0.01	LC-MSMS	*	草

ND：検出せず

<告示・告示日・施行日一覧>

告示1	平成 4年 10月 27日告示分（平成 5年 5月 1日施行）	6	項目
告示2	平成 5年 3月 4日告示分（平成 5年 9月 1日施行）	3	項目
告示3	平成 5年 9月 14日告示分（平成 6年 4月 1日施行）	2	項目
告示4・5	平成 6年 6月 9日告示分（平成 7年 1月 1日施行）	3	項目
告示7	平成 8年 9月 2日告示分（平成 9年 3月 1日施行）	2	項目
告示8	平成 9年 9月 1日告示分（平成 10年 3月 1日施行）	5	項目
告示9	平成10年 10月 12日告示分（平成 11年 4月 1日施行）	3	項目
告示10	平成11年 11月 22日告示分（平成 12年 4月 1日施行）	1	項目
告示12	平成13年 2月 28日告示分（平成 13年 4月1日施行）	1	項目
告示14	平成14年 3月 13日告示分（平成 14年 4月1日施行）	1	項目
告示15	平成17年 11月 29日告示分(平成18年 5月29日施行)	34	項目
告示21	平成19年12月 28日告示分(平成19年12月28日施行)	1	項目
告示33	平成21年6月4日告示分(平成21年12月4日施行予定)	2	項目
*	食品衛生法に該当のない物質	3	項目

系：(草)除草剤 (菌)殺菌剤 (虫)殺虫剤 (調)植物調整剤 (く)くん蒸剤 (殺)薬害軽減剤 (共)共力剤 (ダ)殺ダニ剤
出典(農薬便覧第10版等 2004年8月15日発行 他)

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Intertek Agri Services

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St. Rose, LA. 70087
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Email: noagribulkops@intertek.com

CHEMICAL RESIDUE FREE CERTIFICATE

AGREX INC. February 7, 2007

SAMPLE DESCRIBED AS: U.S. NON-GMO YELLOW WAXY CORN, IN BULK

IDENTIFIED AS: NON-GMO YELLOW WAXY CORN M/V BLEST MARINE

SUBMITTED BY: BLUE WATER SHIPPING CO., Metairie, LA

MALATHION	NEGATIVE
PIRIMIPHOS-METHYL	NEGATIVE
ALUMINIUM PHOSPHIDE	NEGATIVE
ATRAZINE	NEGATIVE
ACETOCHLOR	NEGATIVE
FENITOROTHION	NEGATIVE
GLYPHOSATE	NEGATIVE
GLUFOSINATE	NEGATIVE

"DETECTION LIMIT FOR MALATHION IS SET AT 2.0 PPM AS PER REQUEST"
"DETECTION LIMIT FOR THE OTHER CHEMICALS IS SET AT 1.0 PPM AS PER REQUEST"

Above results are based upon sample submitted to INTERTEK AGRI SERVICES New Orleans Laboratory, for analysis. Any sample identification is reported as submitted and is not verified by INTERTEK AGRI SERVICES New Orleans Laboratory as a representative sample. Sample will be retained for a period of 45 days.

Certificate No. US/39278.34641/07

INTERTEK AGRI SERVICES

Boyce Butler
Director Agri Laboratories USA
New Orleans, Louisiana
/amp

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Email: noagribulkops@intertek.com

CHEMICAL RESIDUE FREE CERTIFICATE

AGREX INC. March 31, 2008

SAMPLE DESCRIBED AS: U.S. NON-GMO YELLOW CORN, IN BULK

IDENTIFIED AS: NON-GMO YELLOW CORN M/V SVETI NIKOLA I

SUBMITTED BY: BLUE WATER SHIPPING CO., Metairie, LA

MALATHION ..... NEGATIVE
PIRIMIPHOS-METHYL ..... NEGATIVE
ALUMINIUM PHOSPHIDE ..... NEGATIVE
ATRAZINE ..... NEGATIVE
ACETOCHLOR ..... NEGATIVE
FENITOROTHION ..... NEGATIVE
GLYPHOSATE ..... NEGATIVE
GLUFOSINATE ..... NEGATIVE

"DETECTION LIMIT FOR MALATHION IS SET AT 2.0 PPM AS PER REQUEST"
"DETECTION LIMIT FOR THE OTHER CHEMICALS IS SET AT 1.0 PPM AS PER REQUEST"

Above results are based upon sample submitted to INTERTEK AGRI SERVICES New Orleans Laboratory, for analysis. Any sample identification is reported as submitted and is not verified by INTERTEK AGRI SERVICES New Orleans Laboratory as a representative sample. Sample will be retained for a period of 45 days.

Certificate No. US/43337.46876

INTERTEK AGRI SERVICES

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Boyce Butler
Director Agri Laboratories USA
New Orleans, Louisiana
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SGS

CHEMICAL RESIDUE FREE CERTIFICATE

September 14, 2009

AGREX, INC.

SAMPLE DESCRIBED AS: U.S. NON-GMO YELLOW CORN, IN BULK

IDENTIFIED AS: NON-GMO YELLOW CORN M/V ASIAN GLORY

SUBMITTED BY: BLUE WATER SHIPPING CO., Metairie, LA

ACETOCHLOR.....LESS THAN 0.05 PPM DETECTED
MALATHION .....LESS THAN 0.1 PPM DETECTED
PIRIMIPHOS-METHYL .....LESS THAN 0.1 PPM DETECTED
ALUMINIUM PHOSPHIDE .....LESS THAN 0.1 PPM DETECTED
ATRAZINE .....LESS THAN 0.1 PPM DETECTED
FENITOROTHION.....LESS THAN 0.1 PPM DETECTED
GLYPHOSATE..... LESS THAN 0.1 PPM DETECTED
GLUFOSINATE.....LESS THAN 0.1 PPM DETECTED

Above results are based upon sample submitted to SGS AGRICULTURAL SERVICES New Orleans Laboratory, for analysis. Any sample identification is reported as submitted and is not verified by SGS AGRICULTURAL SERVICES New Orleans Laboratory as a representative sample. Sample will be retained for a period of 90 days.

Certificate No. 989256.A594902506

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Karin Madere
SGS North America, Inc.
Agricultural Services

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Report of Analysis

Product Name : Waxy Corn Starch

Lot No. : 050111

Date : 2005/04/27

Items for analyses	Results	Detection limits
Sulfur dioxide	0.011g/kg	
Arsenate (as As_2O_3)	Not detected	0.1 ppm
Heavy metal (as Pb)	Not detected	1 ppm
Aflatoxin B_1	Not detected	1 ppb
Aflatoxin B_2	Not detected	1 ppb
Fumonisin B_1	Not detected	0.05 ppm
Fumonisin B_2	Not detected	0.05 ppm
BHC	Not detected	0.02 ppm
DDT	Not detected	0.02 ppm
Dieldrin(including Aldrin)	Not detected	0.01 ppm
Parathion	Not detected	0.05 ppm
Micro-organisms	20/g	
Moulds	20/g	
Thermostable spore-forming micro-organisms	<300/g	
Staphylococcus aureus	Negative/0.01g	
Salmonella	Negative/25g	0
Bacillus cereus	Negative/0.01g	0

Report of Analysis

Product Name : Waxy Starch Y

Lot No. : 090118

Date : 2009/03/06

Items for analyses	Results	Detection limits
Sulfur dioxide	Not detected	0.003g/kg
Arsenate (as As_2O_3)	Not detected	0.1 ppm
Heavy metal (as Pb)	Not detected	1 ppm
Aflatoxin B_1	Not detected	1 ppb
Aflatoxin B_2	Not detected	1 ppb
Fumonisin B_1	Not detected	0.05 ppm
Fumonisin B_2	Not detected	0.05 ppm
Standard plate counts	<300/g	
Molds	90/g	
Yeasts	Negative	
Thermostable spore-forming micro-organisms	<300/g	
Staphylococcus aureus	Negative/0.01g	
Salmonella	Negative/25g	
Bacillus cereus	Negative/0.01g	

Report of Analysis

Product Name : Waxy Starch Y

Lot No. : 100203

Date : 2010/02/23

Items for analyses	Results	Detection limits
Sulfur dioxide	0.013g/kg	
Arsenate (as As_2O_3)	Not detected	0.1 ppm
Heavy metal (as Pb)	Not detected	1 ppm
Aflatoxin B_1	Not detected	1 ppb
Aflatoxin B_2	Not detected	1 ppb
Fumonisin B_1	Not detected	0.05 ppm
Fumonisin B_2	Not detected	0.05 ppm
Standard plate counts	<300/g	
Coliforms	Negative/2.22g	
Molds	50/g	
Yeasts	Negative	
Thermostable spore-forming micro-organisms	<300/g	
Staphylococcus aureus	Negative/0.01g	
Salmonella	Negative/25g	
Bacillus cereus	Negative/0.01g	

APPENDIX D

APPENDIX D

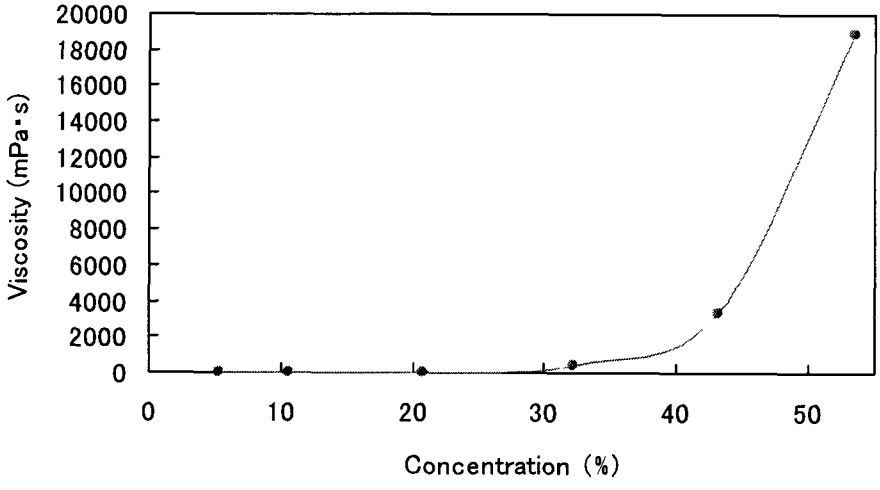
SUMMARY OF THE ANALYTICAL DATA ON THE VISCOSITY AND STABILITY OF CYCLIC DEXTRIN, HIGHLY BRANCHED

APPENDIX D-1
ANALYTICAL DATA ON THE VISCOSITY OF CYCLIC DEXTRIN, HIGHLY BRANCHED

2007/05/17

Viscosity of CCD

1) Viscosity was measured at 23 degree C of temperature and 200 1/s of shear rate by using a rotational viscometer.



APPENDIX D-2
ANALYTICAL DATA ON THE BULK STABILITY OF CYCLIC DEXTRIN, HIGHLY BRANCHED

Ezaki Glico Co., Ltd.
April 15, 2010

Table D-2-1 Long-Term Bulk Stability of Cyclic Dextrin, Highly Branched (up to 6 years)				
Storage Term (months)	**HBCD Content (% of total carbohydrate)**			
	Lot 1 (No. 18.5.31)	**Lot 2 (No. 17.5.10)**	**Lot 3 (No. 16.4.29)**	**Lot 4 (No. 14.10.16)**
0	91.7	94.3	87.7	94.0
25	93.3	-	-	-
36	-	94.3	-	-
47	-	-	90.4	-
77	-	-	-	93.3

HBCD = highly-branched cyclic dextrin

Data of Stability of CCD

2008/06/09

Ezaki Glico Co., Ltd.

Biochem. Res. Lab.

Method of analysis

The contents were determined by HPLC-MALLS-RI method before and after storage at room temperature.

Results

Lot	Before storage		After storage	
	CCD content (%)	Date of analysis	CCD content (%)	Date of analysis
14.10.16	94.0	2002/11/5	92.7	2008/6/5
16.4.29	87.7	2004/5/17	90.4	2008/6/5
17.5.10	94.3	2005/6/23	94.3	2008/6/5
18.5.31	91.7	2006/7/14	93.3	2008/6/5

SUBMISSION END

AM

Glico

EZAKI GLICO CO., LTD.

SENT *VIA* EMAIL

January 31, 2011

Shayla West-Barnette, Ph.D.
Division of Biotechnology and GRAS Notice Review
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Withdrawal of Generally Recognized As Safe (GRAS) Exemption Notices for Alpha-D-Glucan Branching Enzyme Preparation and Cyclic Dextrin, Highly Branched

Dear Dr. West-Barnette:

This letter is to inform you that we would like to withdraw our GRAS Exemption Notices for 1,4-alpha-D-Glucan Branching Enzyme Preparation (GRN 361) and Cyclic Dextrin, Highly Branched (GRN 358), which were submitted to your office on October 8, 2010. This will allow us more time to adequately address the questions raised by the Agency regarding the aforementioned Notices.

Thank you for your kind attention to this matter. Please contact me should you have any questions regarding the withdrawal of these Notices.

Sincerely,

(b) (6)

Takashi Kuriki
Chief Scientific Officer