Dextrin

Handling/Processing

Identification of Petitioned Substance

Chemical Name:
Dextrin

CAS Number:
9004-53-9

Other Names:
Pyrodextrin
Torrefaction dextrin

Other Codes:
EINECS No. 232-675-4
INS No. 1400

Characterization of Petitioned Substance

Composition of the Substance:

The petitioned substance is partially hydrolyzed starch converted by heat alone, or by heating in the presence of suitable acids and buffers, in some cases followed by enzymatic treatment, from unmodified native starches (e.g. corn, waxy maize, wheat, rice, etc.), which is a polysaccharide comprising glucose monomers joined in 1,4-linkages. Dextrin is built up of D-glucose, which contains 6 carbon atoms, 12 hydrogen atoms, and 6 oxygen atoms to form a ring structure (Potter, 1973), and has an intermediate chain length. Its molecular formula is $(C_6H_{10}O_5)_n \cdot xH_2O$ (Merck Index, 2006).

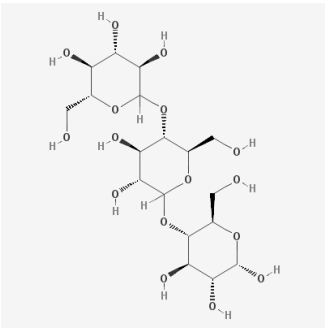

Figure 1. Dextrin Chemical Structure

Properties of the Substance:

Dextrin(s) refers to a group of hydrophilic (water loving) polysaccharides and is an incompletely hydrolyzed starch. Dextrins are also a stage in the normal digestion of starch occurring in the human gastrointestinal tract. They represent a broad range of products with considerably smaller molecular size than native starch. They are similar to starch in that they are composed principally of alpha-D-anhydroglucose units joined through 1,4-linkages; they differ from starch in that dextrinization reduces the molecular weight and increases branching in the molecule (SCOGS Report No. 75). The petitioned substance occurs as free-flowing white, yellow, or brown powders and consists of polygonal, rounded, oblong, or truncated granules (FCC, 2010-2011). Dextrins have low viscosity; they are partially to completely soluble in water but insoluble in alcohol (Hassid, 1993; Merck Index, 2006).

There are three derivatives (Burdock, 1997; Merck Index, 2006): (1) White dextrin has light color, odorless, and soluble in cold water (solubility ranging from 5 to over 90%). When dissolved in cold water, it gives a red color with iodine, and, when soluble in hot water, it gives a blue color with iodine. (2) Yellow dextrin (canary dextrin) has light brown to yellow color, slight odor, and low viscosity; it is very soluble in cold

water. (3) British gum (starch gum) has dark brown color, odorous, and high viscosity (compared to yellow and white dextrins); it is very soluble in cold water, giving a reddish-brown color with iodine.

Specific Uses of the Substance:

Dextrin, as a food additive, is used as a formulation aid, a processing aid, a stabilizer and thickener, and/or a surface-finishing agent in accordance with FDA §184.1277(c)(1).

In the petition, it stated that dextrin is used in a variety of food applications for nutritional and functional benefits. It can be served as a source of soluble fiber in foods and beverages. The anticipated use of the dextrin is for French fries, batter and breading, soups, sauces, confections, beverages, snacks, cereals, puddings, yogurts, and baked goods. Typical use levels for dextrin in foods and beverages, in accordance with the petitioner, are between 1-10%.

Other uses of this substance include excipient for dry extracts and pills; preparing emulsions and dry bandages; thickening dye pastes and mordants used in printing fabrics in fast colors; sizing paper and fabrics; printing tapestries; preparing felt; manufacturing printer's inks, glues and mucilage; polishing cereals; in matches, fireworks, and explosives (Merck Index, 2006).

Approved Legal Uses of the Substance:

EPA— Dextrin (CAS No. 9004-53-9) is listed under 40 CFR §180.950 (e) Specific chemical substances. Residues resulting from the use of these chemicals (such as dextrin) as either an inert or an active ingredient in a pesticide chemical formulation are exempted from the requirement of a tolerance, if such use is in accordance with good agricultural or manufacturing practices.

FDA— 21 CFR §184.1277 Dextrin is under *Listing of Specific Substances Affirmed as DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE*. This ingredient is used in food with no limitation other than current good manufacturing practice.

Action of the Substance:

In general, dextrin has low viscosity, cold water solubility, and tendency to form gels or pastes. Its actions in different usages are as follows:

- A formulation aid — Dextrin used to promote or produce a desired physical state or texture in product.
- A processing aid — Petitioned substance used as manufacturing aids to enhance the appeal or utility of a food or food component.
- A stabilizer and thickener — It is used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions.
- A surface-finishing agent — This substance used to increase palatability, preserve gloss, and inhibit discoloration of foods.
- A source of soluble fiber — Because the non-digestible glucoside linkages lead to incomplete hydrolyzation, only a small percentage of dextrin is absorbed in the small intestine and the rest is slowly fermented in the large intestine (Slavin et al., 2009).

Status

Domestic:

EPA — Dextrin (CAS No. 9004-53-9) is listed on List 4A – *Minimal Risk Inert Ingredients – By Chemical Name*, updated August 2004. Dextrin with EPA PC (Pesticide Chemical) Code 084503 is included on *Alphabetic Active Chemical Code List*, March 31, 2008 edition, of *Pesticide Data Submitters List*. In addition, dextrin is

listed under the subsection 180.950 (e) *Specific chemical substances* of the section 180.950 *Tolerance exemptions for minimal risk active and inert ingredients*.

FDA — Dextrin is affirmed as GRAS, see the above, the Approved Legal Uses of the Substance section. Dextrin may be used as a formulation aid, a processing aid, a stabilizer and thickener, and a surface-finishing agent.

International:

Codex — "Dextrins, roasted starch" is listed in Table Three (*Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP*) of Codex General Standard for Food Additives. This substance was adopted in 1999. It is classified as an emulsifier, a stabilizer, and a thickener. 'Dextrins' was evaluated previously for an ADI[1] for man by the Joint FAO/WHO Expert Committee on Food Additives in 1969 and 1974. "Not specified" for estimate of acceptable daily intake for man is stated in the report of WHO Food Additives Series 17 (1982).

European Union — "white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment …"are not considered to be food additives. See Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

Canada — Dextrin is listed in Natural Health Products Ingredients Database. Purposes: binder, diluent, emulsion stabilizer, stiffening agent, thickening agent, viscosity increasing agent.

IFOAM — Not listed.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

The petitioned substance, dextrin, is partially hydrolyzed starch produced by a chemical process called hydrolysis (Wurzburg, 1992). It is prepared by using dry heating or roasting unmodified starch with or without an acid or alkaline catalyst (Burdock, 1997). The acid catalysts include hydrochloric, phosphoric, and nitric acid; the alkali catalysts include sodium hydroxide and hydrolysable salts of weak acids, such as carbonates, hydrogen carbonates, perchlorates, and hypochlorites (Tomasik et al., 1989).

Unmodified starch is usually acidified with small amounts of acid and placed in heated, agitated vessels called reactors or roasters. The temperature is increased at a controlled rate and then maintained at a maximum temperature for varying lengths of time. The resulting product is cooled, blended, and sometimes aged (Burdock, 1997).

A fluid bed technique can also be used. Unmodified starch is placed in a reactor and suspended or fluidized in a stream of heated air. The starch is then acidified and, as in the conventional or "roaster" process, heated under controlled conditions of time and temperature until the desired end product is attained. With the several degrees of freedom possible in such processes, a range of dextrin with widely varying properties is produced (Burdock, 1997).

In some cases, starch is heated with acid and followed by enzymatic (amylase) treatment to form indigestible polysaccharides called resistant dextrin (including maltodextrin). Resistant dextrin is a class of soluble fiber (Slavin et al., 2009; IOM, 2005).

[1] Acceptable Daily Intake.

[Note: Burdock (1997) has indicated that the specific chemistry of the dextrinization process is not established, but many theories have been advanced. Certainly, the process reduces the strength of the chemical bonds which give the starch granule its integrity and brings about molecular scission(s) that both reduce molecular size and alter molecular arrangement. In those cases where acids are present, simple hydrolytic cleavage is believed to occur. Because of altered paste viscosities and congealing characteristics, preferential scission of specific chemical bonds producing these properties probably occurs. In some of the most highly converted dextrin, scission followed by recombination of the fragments is indicated.]

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources. (7 U.S.C. § 6502 (21))

In general, dextrin is prepared by dry heating corn, waxy milo, potato, arrowroot, wheat, rice, tapioca, or sago starches; or by dry heating the starches after treatment with safe and suitable alkalis, acids, or pH control agents (21 CFR §184.1277).

Commercially, there are three types of dextrin. Each type represents a range of products depending on the specific temperature, acid concentration, and time of reaction employed. Product properties also depend on the starch source (WHO Food Additives Series 17, 1982; Wurzburg, 1992; and Burdock, 1997):

(1) White dextrin — It is manufactured by heating dry starch in the presence of acid (such as hydrochloric acid) at a low temperature, generally below 150° C, for a short period of time. White dextrin may also be obtained by further continuing the acid process for making thin boiling starches to yield lower solubility products. They represent a broad range of products with considerably smaller molecular size than native starch.

(2) Yellow or canary dextrin — It is manufactured in a similar manner as white dextrin, but at a higher temperature, more time, but using less acid. The high water solubility products may be produced. Apart from depolymerization, a good deal of internal rearrangement occurs with formation of highly branched molecules.

(3) British or starch gum — It is manufactured by adding little or no acid (in some cases, buffers are used), and high temperatures. British gum is not as low in viscosity as yellow dextrin or white dextrin.

Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Dextrin is produced in the human body by an enzyme called amylase which presents in human saliva. The salivary amylase mixes with the food in the mouth, and then acts on the starch in a slightly alkaline medium to convert it to dextrin (Guthrie, 1975).

In *Revised Monograph–Dextrin*, the Committee on Food Chemicals Codex of Food and Nutrition Board of Institute of Medicine (IOM) (1996) has reported that dextrin is partially hydrolyzed starch converted by heat alone, or by heating in the presence of suitable food-grade acids and buffers, from any of several grain- or root-based unmodified native starches (e.g., corn, waxy maize, high amylose, milo, waxy milo, potato, arrowroot, wheat, rice, tapioca, sago, etc.).

No information sources reviewed specifically address non-synthetic dextrin.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices. (7 CFR § 205.600 (b)(5))

The petitioned substance (dextrin, CAS No. 9004–53–9) is affirmed as generally recognized as safe (GRAS) in 21 CFR §184.1277. In accordance with FDA, the affirmation of dextrin as GRAS as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use (§184.1277):

- The ingredient is used as a formulation aid as defined in §170.3(o)(14); as a processing aid as defined in §170.3(o)(24); as a stabilizer and thickener as defined in §170.3(o)(28); and as a surface-finishing agent as defined in §170.3(o)(30).
- The ingredient is used in food at levels not to exceed current good manufacturing practice.

The following are excerpts from 21 CFR Part 170 *Food Additives* §170.3 *Definitions*:

> "§170.3 (o)(14) Formulation aids: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.
> §170.3 (o)(24) Processing aids: Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculants, filter aids, and crystallization inhibitors, etc.
> §170.3 (o)(28) Stabilizers and thickeners: Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.
> §170.3 (o)(30) Surface-finishing agents: Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings."

This GRAS substance was evaluated by the Select Committee on GRAS Substances (SCOGS) in 1975. The SCOGS concluded that there was no evidence in the available information on dextrin that demonstrated, or suggested reasonable grounds to suspect a hazard to the public when they were used at levels at that time or might reasonably be expected in the future (SCOGS Report No. 75).

In addition, dextrin is listed under *Everything Added to Food in the United States (EAFUS)* in FDA/CFSAN's the Priority-based Assessment of Food Additives (PAFA) database. The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS.

Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative. (7 CFR § 205.600 (b)(4))

In the FDA regulation (21 CFR §184.1277), dextrin may be used as a surface-finishing agent as defined in §170.3(o)(30)—substances used to increase palatability, preserve gloss, and inhibit discoloration of foods.

However, no information sources reviewed specifically address the primary function/purpose of dextrin as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics. (7 CFR § 205.600 (b)(4))

As described in Evaluation Question (EQ) #4, dextrin may be used as a formulation aid (including carriers, binders, fillers, plasticizers, film-formers, tableting aids, etc.) to promote or produce a desired physical state or texture in food; as a processing aid (including clarifying agents, clouding agents, catalysts, flocculants, filter aids, crystallization inhibitors, etc.) to enhance the appeal or utility of a food or food component; as a stabilizer and thickener (including suspending and bodying agents, setting agents, jellying agents, bulking agents, etc.) to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions; and as a surface-finishing agent (including glazes, polishes, waxes, and protective coatings) to increase palatability, preserve gloss, and inhibit discoloration of foods.

According to the petition, dextrin can be used to provide structure to foods and to replace fat and shortening to lower fat content in foods. It can also be used as a bulking agent in sweet baked goods to

lower the sugar content. Dextrin can be added to a coating for confections or fried foods to increase shelf-life and/or crisp texture; applied to the food surface for adhering spices and other particulates, in addition to improve shine and appearance; used as a carrier in spray dried vitamins and flavors to aid in the process as well as protect the encapsulated materials from oxidation; and added to the reduced fat or sugar beverages to provide mouth feel and flavor improvement.

No information sources were identified to suggest that the petitioned substance be used primarily to recreate nutritive values lost in processing.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used. (7 CFR § 205.600 (b)(3))

"Dextrin is used in a variety of food applications for nutritional and functional benefits" is stated in the petition. Dextrin can be used as fat replacer to lower calorie content of foods. In Kirk-Othmer Food and Feed Technology, Wiley (2008) has indicated that dextrin is well known for its ability to mimic several of fat sensations, including mouth-coating, the melting sensation, and the richness of fat. It is a traditional ingredient modified to provide enhanced functionality in reduced-fat systems. Dextrin provides 4 kcal/g compared with 9 kcal/g of fat. It is commonly used in salad dressings, puddings, spreads, frozen desserts, and dairy foods.

Dextrin can also serve as a source of soluble fiber in foods and beverages or as a fiber supplement. In "*Soluble fiber dextrin enhances the satiating power of beverages*" study (Monsivals et al., 2011), it has concluded that the supplementation of foods and beverages with soluble fiber dextrin is one way to increase fiber in the diet that might prove effective in helping consumers control their appetite and energy intake. In addition, Slavin and co-workers (2009) have reported that supplementation with soluble fibers may be useful in individuals at risk of a lower than recommended dietary fiber intake. According to *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* by Food and Nutrition Board of Institute of Medicine (IOM) (2005), an Adequate Intake (AI) for total fiber (dietary fiber[2] and functional fiber[3]) in foods is set at 38 and 25 g/day for young men and women, respectively, based on the intake level observed to protect against coronary heart disease.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance. (7 CFR § 205.600 (b)(5))

According to the specification of dextrin in Food Chemical Codex (2010-2011), it stipulates the impurity acceptable criterion for a heavy metal is not more than 1 mg/kg of lead.

No information sources can be identified to suggest that the petitioned substance contains residues of heavy metals or other contaminants in excess of FDA's Action Levels for Poisonous or Deleterious Substances in Human Food.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i))

The petitioned substance is originated from starch, a naturally occurring carbohydrate polymer. Natural macromolecules contain hydrolysable linkages that are susceptible to biodegradation by the hydrolytic enzymes of microorganisms (Bohlmann, 2005). No adverse effect to soil organisms and crops would be anticipated. The dextrin would not be expected to persist in the environment.

[2] Dietary Fiber consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.
[3] Functional Fiber consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.

During the manufacturing process, dextrin roasters and starch/dextrin transfer, storage, and loading facilities employ fabric filters to recover starch/dextrin emissions in dry form for immediate recycle to the process. [Note: A dextrin roaster is a reactor vessel, or a series of vessels, in which starch is reacted, through the addition of heat and/or chemicals, to form the dextrin. Starch/dextrin transfer, storage, and loading facilities include any facility used to blend, mix, mill, grind, screen, convey, transfer, store, or load for shipment (including, but not limited to, bag, truck, and railcar). This also includes the bag dumping of additives into the starch for dextrin producing.] Since the pollutant is also the product, source reduction cannot be practiced in this industry (i.e., nothing can replace the starch). However, pollution prevention is exhibited in the industry through the total use of the scrubber and fabric filter "waste" streams in in-process recycling and the loading of trucks and railcars using vacuum pressure systems (EPA-453/R-94-060, 1994).

In the document of *Rationale for Now Source Performance Standards: Starch Production Plants* (1994), EPA has stated that there are no solid or liquid waste impacts associated with the standards. This is because all particulate matter recovered by control devices as well as all water used in wet scrubbers is typically recycled back into plant processes.

According to the petitioner, any effluent from the manufacture of dextrin would be treated within the limits established under waste water permits and sent to a Publicly Owned Treatment Works (POTW)[4]. There may also be particulate matter generated during the manufacturing process. Particulate matter would be collected by dust collectors and/or scrubbers. Any remaining air emissions are within the Title V air permit[5] limits. Any waste dextrin product would go into a recycle stream and used in downgraded products or go to a landfill. Recycling programs at the plants recover approximately 95% of the waste.

In the EPA regulations, "Dextrins, CAS No. 9004-53-9" is listed under the subsection (e) *Specific chemical substances* of § 180.950 *Tolerance exceptions for minimal risk active and inert ingredients*, in addition to on EPA List 4A – *Minimal Risk Inert Ingredients* of *List of Inert Pesticide Ingredients*. The determination that a chemical is minimal risk is based on a recognition of the overall safety of the chemical (such as very low toxicity or practically non-toxic) considering the widely available information on the chemical's known properties, and a history of safe use under reasonable circumstances. Minimal risk substances on List 4A are recognized as safe for use in all pesticide products subject only to good agricultural or good manufacturing practices (EPA, 2010).

For occupational exposure, it is a possible physical irritant from dust particles. In case of eye contact, particulates may scratch eye surfaces and cause mechanical irritation. The petitioned substance can produce a nuisance dust which should be maintained below a time weighted average of 10 mg/m^3 in accordance with Material Safety Data Sheet (MSDS) in the petition. Fine dust dispersed in air, in sufficient concentrations and in the presence of an ignition source, is a potential dust explosion hazard. Personal respirator (NIOSH[6] approved) for conditions of use where exposure to the dust or mist is apparent, a half-face dust/mist respirator may be worn; for emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator (MSDS, Reagents, Inc.).

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance. (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and 7 U.S.C. § 6518 (m) (4))

[4] Publicly owned treatment works (POTW) collect wastewater from homes, commercial buildings, and industrial facilities and transport it via a series of pipes, known as a collection system, to the treatment plant. The POTW removes harmful organisms and other contaminants from the sewage so it can be discharged safely into the receiving stream.

[5] Title V air permit also called a title V operating permit that most large sources and some smaller sources of air pollution are required to obtain. This requirement comes from Title V of the Clean Air Act, as amended in 1990. Most title V permits are issued by State and local permitting authorities.

[6] National Institute for Occupational Safety and Health.

'Dextrins' was evaluated previously for an acceptable daily intake (ADI) for man by the Joint FAO/WHO Expert Committee on Food Additives in 1969 and 1974. In 2008, a monograph of *Dextrins* (WHO Food Additives Series 17) was published with additional available data. The committee commented that "these substances are regarded as identical to the intermediates formed in the normal digestion of starch and normal constituents of food." Moreover, "Not specified" was assigned for 'estimate of ADI for man' under the evaluation section of this monograph. The statement "ADI not specified" means that, on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of an acceptable daily intake in mg/kg body weight is not deemed necessary (WHO Food Additives Series 17, 2008).

According to the Select Committee on GRAS Substances (SCOGS) Report on "Dextrins" (1975), animal feeding studies showed dextrins to be digested and metabolized to a limited degree without toxic effects when fed at levels many times greater than those present from use of these products as a direct food additive, or at levels that are orders of magnitude greater than might occur by migration from food packaging materials containing dextrins. Therefore, the committee concluded that "There is no evidence in the available information on dextrins and corn dextrin that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might be reasonably expected in the future."

In the report of *A Review of the Role of Soluble Fiber in Health with Specific Reference to Wheat* Dextrin, Slavin and co-workers (2009) stated "The evidence suggests that soluble fibers help to regulate the digestive system, may increase micronutrient absorption, stabilize blood glucose, and lower serum lipids, may prevent several gastrointestinal disorders, and have an accepted role in the prevention of cardiovascular disease." Soluble fibers could also promote the growth of colonic bacterial flora (prebiotic effect). They concluded that supplementation with soluble fibers (e.g. wheat dextrin) may be useful in individuals at risk of a lower than recommended dietary fiber intake. Institute of Medicine (2005) also reported that "Resistant dextrins can potentially be classified as Functional Fibers when sufficient data on physiological benefits in humans are documented."

In addition, both dietary and functional fibers can promote physiological processes that are associated with satiety. For example, they can slow gastric emptying, reduce the glycemic index[7] of foods, modify the release of gastrointestinal hormones, and modify the absorption of other nutrients (Monsivais et al., 2010; Howarth et al., 2001).

Dextrin can be made from a wide variety of starch, such as wheat, corn, rice, potato, or tapioca. It is important for people with food allergies or intolerances to know the origin of the dextrin. For instance, wheat-based dextrin may be found traces of gluten, the product containing this dextrin should be avoided by the individuals with wheat allergies or by the people with celiac disease who cannot tolerate gluten.

Evaluation Question #11: Provide a list of organic agricultural products that could be substituted for the petitioned substance. (7 CFR § 205.600 (b)(1))

As described in EQs #1 and #2, dextrin is partially hydrolyzed starch converted by heat alone, or by heating in the presence of suitable acids and buffers, or by heating acids and enzymes, from any of several grain- or root-based unmodified native starches (e.g., corn, waxy maize, high amylose, milo, waxy milo,

[7] The glycemic index (GI) is a ranking of carbohydrates on a scale from 0 to 100 according to the extent to which they raise blood sugar levels after eating. Foods with a high GI are those which are rapidly digested and absorbed and result in marked fluctuations in blood sugar levels. Low-GI foods, by virtue of their slow digestion and absorption, produce gradual rises in blood sugar and insulin levels, and have proven benefits for health.

potato, arrowroot, wheat, rice, tapioca, sago, etc.). Dextrin consists of D-glucose units, which are primarily linked with alpha-1-4 glycosidic bonds, connected in chains of variable length.

Maltodextrin, made by partially hydrolyzing starch, is typically composed of a mixture of chains that vary from three to nineteen glucose units long (Sugar Association, 2011). According to 21CFR §184.1444, maltodextrin is affirmed as GRAS. It is a nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by alpha-1-4 bonds and that has a dextrose equivalent[8] (D.E.) of less than 20. Maltodextrin is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes (21 CFR §184.1444). The term "maltodextrin" can be applied to any starch hydrolysis product that contains fewer than 20 glucose units linked together, in accordance with the Sugar Association.

Maltodextrin has been utilized by the food industry for its low viscosity, low sweetness, clarity, and bland flavor (Luallen, 2002). It can be used as an anticaking and free-flowing agent, bulking agent, stabilizer and thickener, and surface-finishing agent (FCC, 2010-2011). In addition, maltodextrin is used as a formulation aid (e.g. act as a carrier or encapsulating agent for essential oils and other flavors) and processing aid (e.g. act as a crystallization inhibitor for frozen foods); it is a starch-based fat replacer (Macrae et al., 1993).

Based on the database of NOP Certified Operations, as of 2010, following is a tabulated list for the names and addresses of companies producing maltodextrin and rice dextrin (NOP Certified Operations, 2010):

PRODUCT	COMPANY	ADDRESS
Maltodextrin	Laxon Corporation	421 Amapola Ave., Torrance, CA 90501
Maltodextrin	Seven Bridges Cooperative Microbrewery, Inc.	325A River St., Santa Cruz, CA 95060
Maltodextrin	Ag Commodities, Inc. aka LFO, B20, AGRP	2913 El Camino Real, Suite 620, Tustin, CA 92782
Maltodextrin	Marroquin Organic International, Inc.	303 Potrero Street, Suite 18, Santa Cruz, CA 95060
Maltodextrin	Newport Flavours & Fragrances	833 N. Elm Orange, CA 92868
Tapioca maltodextrin	Grain Processing Corporation	1600 Oregon Street, Muscatine, IA 52761
Maltodextrin	SP 272 - Corn Products Brasil Ingredientes Industrias Ltda	Rua Paula Bueno,Nº 2935 Jd. Alvorada Mogi Guaçu - Sp Cep: 13840000, Brazil
Maltodextrin	Habib-ADM Ltd.	2nd floor UBL Building, I. I. Chundrigar Road, Karachi, 74000, Pakistan
Tapioca maltodextrin	H-H Technology/Zanaceutica	Calle Marcos Farfan 3181.Urb. Industrial Independencia. Lima, Peru
Rice dextrin	NanJing Axiom Foods Co., Ltd.	Room 101, Building No.2, World Windows Software Zone, No.12, DingHaiMen, Nanjing, Jiangsu, 210013, China

References

[8] Hydrolyzed products are commonly characterized by their degree of hydrolysis, expressed as dextrose equivalent (D.E.), which is the percentage of reducing sugar calculated as dextrose on dry-weight basis.

APA (American Pharmacists Association). 2007. A Pharmacist's Guide to Fiber and Fiber Supplements. The One Minute Counselor. Reviewed by Newton, G.D. http://www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=11336&TEMPLATE=/CM/ContentDisplay.cfm

Bohlmann, G.M. 2005. General Characteristics, Processability, Industrial Applications and Market Evolution of Biodegradable Polymers. In: Bastioli, C., editor. Handbook of Biodegradable Polymers. Rapra Technology Limited, Shropshire, UK, p 186. http://deadman.x10hosting.com/Handbook_of_Biodegradable_Polymers.pdf

Burdock, G.A. Dextrin. 1997. In: Encyclopedia of Food and Color Additives. Boca Raton, FL: CRC press. p 793-796

CODEX STAN 192-1995, Table 3. In: Codex General Standard for Food Additives. http://www.codexalimentarius.net/gsfaonline/CXS_192e.pdf

Dextrins (536. Dextrins). 1982. In: WHO Food Additives Series 17. Toxicological evaluation of certain food additives. WHO Food Additives Series, No. 17, nos 521-553 on INCHEM. http://www.inchem.org/documents/jecfa/jecmono/v17je16.htm

Dextrin. 2008. In: The Columbia Encyclopedia. Sixth Edition. Encyclopedia.com. (February 9, 2011) http://www.encyclopedia.com/doc/1E1-dextrin.html

Dextrin. 2010. In: Natural Health Products Ingredients Database —Health Canada. 7-13-2010. http://webprod.hc-sc.gc.ca/nhpid-bdipsn/ingredReq.do?id=140&lang=eng

Dextrin. MSDS. Reagents, Inc. http://www.reagents.com/pdf/MSDS/2-19450.pdf

EC No 1333/2008. Article 3. In: REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives. Official Journal of the European Union. L 354/16-33. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF

EPA, 40 CFR §180.950 Tolerance exemptions for minimal risk active and inert ingredients. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a30e2d7a68126a0db932cabc8297b957&rgn=div8&view=text&node=40:23.0.1.1.28.4.19.7&idno=40

EPA, Alphabetic Active Chemical Code List. In: Pesticide Data Submitters List. March 31, 2008 edition. http://www.for-the-love-of-cats.com/support-files/dslchem.pdf.

EPA, List 4A-Minimal Risk Inert Ingredients – By Chemical Name. In: List of Inert Pesticide Ingredients. Updated August 2004. EPA, Office of Pesticide Programs.

EPA, Inert Ingredients Permitted in Pesticide Products. 2010. In: Pesticides: Regulating Pesticides. Internet last update 12/8/2010. http://www.epa.gov/opprd001/inerts/

EPA, Rationale for New Source Performance Standards Starch Production Plants. 1994. EPA-453/R-94-060. US EPA Office of Air and Radiation, Office of Air Quality Planning and Standards, Research Triangle Park, NC. Aug. 1994.

Food Chemicals Codex (FCC). 2010-2011. Dextrin. In: Food Chemicals Codex. 7th ed. Rockville, MD: The US Pharmacopeial Convention. p 280-282.

Food Chemicals Codex (FCC). 2010-2011. Maltodextrin. In: Food Chemicals Codex. 7th ed. Rockville, MD: The US Pharmacopeial Convention. p 617.

FDA, 21 CFR §170.3 Definitions. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=455948b57c6c700436a0f490c7d3f56a&rgn=div8&view=text&node=21:3.0.1.1.1.1.1.1&idno=21

FDA, 21 CFR §184.1277 Dextrin. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=60a8aebd345d69c03f8b5a8fbe94fb4c&rgn=div5&view=text&node=21:3.0.1.1.14&idno=21#21:3.0.1.1.14.2.1.67

FDA, 21 CFR §184.1444 Maltodextrin. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=22032252960100f29088d98807155182&rgn=div8&view=text&node=21:3.0.1.1.14.2.1.122&idno=21

FDA, Dextrin, Doc No. 2012. In: Everything Added to Food in the United States (EAFUS). FDA/CFSAN's the Priority-based Assessment of Food Additives (PAFA) database..
http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=eafusListing&id=869

FDA, SCOGS Report No. 75. 1975. Dextrins. In: Database of Select Committee on GRAS Substances (SCOGS) Reviews.
http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=102

Guthrie, H.A. 1975. Carbohydrate. In: Introductory Nutrition. 3rd ed. Saint Louis: The C.V. Mosby Company. p 26

Hassid, W.Z. Dextrin. 1993. In: McGraw-Hill Encyclopedia of Science & Technology 5. 7th ed. NewYork: McGraw-Hill, Inc. p 172.

Howarth, N.C., Saltzman, E., and Roberts, S.B. 2001. Dietary fiber and weight regulation. Nutrition Reviews, Vol. 59. No. 5. p 129-139.

Institute of Medicine (IOM). 1996. Revised Monograph - Dextrin. Committee on Food Chemicals Codex, Food and Nutrition Board of Institute of Medicine. National Academy of Science.
http://www.nap.edu/html/fcc/dextrin.pdf

Institute of Medicine (IOM). 2005. Dietary, Functional, and Total Fiber. In: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Food and Nutrition Board, Institute of Medicine of the National Academies. The National Academies Press. Washington, D.C. p 339-421. http://www.nap.edu/openbook.php?record_id=10490&page=339

Luallen, T. E. 2002. A Comprehensive Review of Commercial Starches and Their Potential in Foods. In: Branen, A. L., Davidson, P. M., Salminen, S., and Thorngate III, J. H., editors. Food Additives. 2nd Ed. New York: Marcel Dekker, Inc.

Macrae, R., Robinson, R. K., and Sadler, M. J. editors. 1993. Dextrins. In Encyclopaedia of Food Science Food Technology and Nutrition, Vol. Two. New York, Academic Press. p 1325

Merck Index. 2006. Dextrin (Monograph No. 2953). In: the Merck Index an Encyclopedia of Chemicals, Drugs, and Biologicals. 14th ed. Whitehouse Station, NJ: Merck & Co., Inc. p 2950.

Monsivais, P., Carter, B.E., Christiansen, M., Perrigue, M.M., and Drewnowski, A. 2010. Soluble fiber dextrin enhances the satiating power of beverages. In: Appetite. Elsevier Ltd. doi:

10.1016/j.appet.2010.10.010. Volume 56, Issue 1, p 9-14. Available online Nov. 4, 2010. www.elsevier.com/locate/appet

Potter, N.N. 1973. Constituents of Foods: Properties and Significance. In: Food Science. 2nd ed. Westport, CT: the AVI Publishing Company, Inc. p 36-58.

Slavin, J., Savarino, V., Paredes-Diaz, A., and Fotopoulos, G. 2009. A review of the role of soluble fiber in health with specific reference to wheat dextrin. Journal of International Medical Research. Vol. 37. No. 1. p 1-17. http://docserver.ingentaconnect.com/deliver/connect/field/03000605/v37n1/s1.pdf?expires=1299710809&id=61639428&titleid=75001442&accname=USDA+National+Agricultural+Lib&checksum=B5F6B815F91847ACBAED254C83D1EDF7

Sugar Association: Other Caloric Sweeteners [internet]. Washington, DC: © The Sugar Association, Inc. [Accessed 2010, March 21]. http://www.sugar.org/other-sweeteners/other-caloric-sweeteners.html#top

Tomasik, P., Wiejak, S., and Palasinski, M. 1989. The Thermal Decomposition of Carbohydrates. Part II. The Decompostopm of Starch. In: Tipson, R. S. Advances in Carbohydrate Chemistry and Biochemistry. Academic Press Inc. Vol. 47. p 279-345.

USDA, NOP Certified Operations. 2010. http://apps.ams.usda.gov/nop/

Wiley, L. 2008. Fat Replacers. In: Kirk-Othmer Food and Feed Technology. Vol.1. p 393-426

Wurzburg, OB. 1992. Starch in the Food Industry. In: Furia, TE, editor. CRC Handbook of Food Additives. 2nd ed. Volume 1. Roca Raton, FL: CRC Press. p 361-395.