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FMC BioPolymer

August 22, 2001

National Organic Standards Board
c/o Robert Pooler
Agricultural Marketing Specialist
USDA/AMS/TM/NOP
Room 2510-So.
Ag Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

Dear Mr. Pooler:

Subject: Resubmission of request to revise 7 CFR 205.605 to include konjac flour.

Prior to the July 13, 2000 Federal Register publication addressing the procedure for petitioning amendments to the National List, we provided documentation to support the inclusion of the food gum, konjac flour, to the National Organic List.

FMC BioPolymer is a major supplier of ingredients and technologies to the food industry offering a range of products for texture, structure and stabilization. The primary food ingredients produced by FMC BioPolymer are carrageenan, cellulose gel, konjac flour, alginic acid and alginates.

Title 7 CFR Section 205.605 as published in the Federal Register of December 20, 2000, lists synthetic and nonsynthetic substances that would be permitted for use in processed products labeled as organic or "made with" specified organic ingredients. We request that the list be revised to include konjac flour in 7 CFR 205.605 (a) nonsynthetics.

Konjac flour (also referred to as "yam flour") is the substance obtained from tubers of the *Amorphophallus* species. It was established as a food in Asia more than 600 years ago and is processed into products such as konjac curd, konjac noodles, and it is used in bread, cakes, jams and jellies. It appears to have been introduced in the United States around 1899. The US Food and Drug Administration has acknowledged that it is a food. Konjac flour is a soluble fiber that functions as a gelling agent, stabilizer/thickener, film former and a fat replacer. It is not mutagenic and it has not exhibited toxicological effects in human and animal feeding studies.

Appropriate documentation to support this request is enclosed for review.

Additional questions concerning the contents of this petition can be addressed to my attention.

Sincerely,



Eunice M. Cuirle
Manager, Global Regulatory Affairs
Tel: (215) 299-6999

Konjac flour (also known as yam flour) has been used for centuries in Asian countries as the principal food ingredient in foodstuffs such as noodles, bread, cakes and jam. The governments of Argentina, Canada and the United States of America consider konjac flour to be a food ingredient when used in foods for technological functions like those of its traditional use in Oriental foods. Australia and the Asian nation consider konjac flour a food; in the same way wheat flour is a food in Western diets.

In the Western diet, konjac flour is used as a gelling agent and stabilizer/thickener; its functional properties are similar to those for food ingredients such as gelatin, pectin, modified starches and vegetable gums. In the United States, the USDA-FSIS classifies konjac flour as a binder in meat and poultry products and subject to the regulations that apply to starchy vegetable flours.

Basic Chemistry

Konjac is the generic name for the flour formed from grinding the tuber (root) of the *Amorphophallus konjac* plant (Elephant yam). This natural ingredient has been used in Asia for centuries in traditional foods such as noodles, and other food products including gels which are stable in boiling water. Today konjac is used to prepare products ranging from heat-stable formed foods to thermally-reversible gelled desserts.

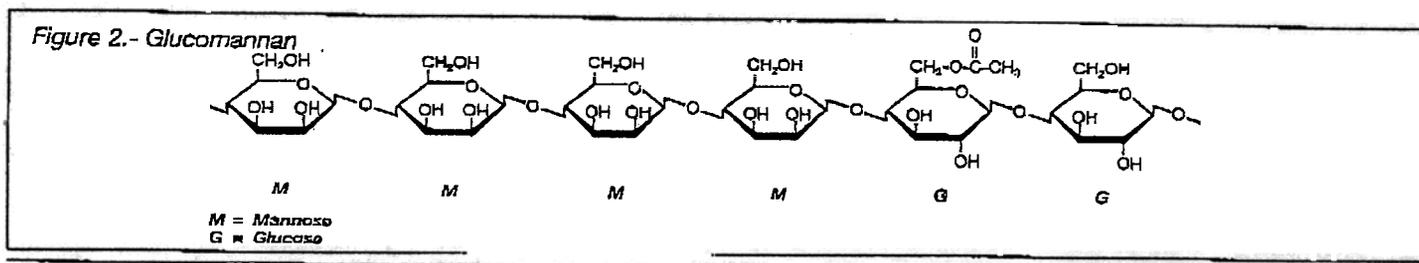
Nutricol® konjac flour is a food ingredient containing a high molecular weight polysaccharide

classified as a glucomannan. The molecular structure is comprised of mannose and glucose chains in a molar ratio of 1.6 to 1 respectively with beta 1-4 linkages, as shown in the chemical structure in Figure 2.

The average molecular weight is between 200,000 to 2,000,000 daltons and is typically 1,000,000 daltons, which accounts for konjac's high pseudoplastic viscosity. The glucomannan molecule, the functional component of konjac flour, has short side branches and

acetyl groups randomly present at the C-6 position of a sugar unit. The acetyl groups frequently range from one per six sugar units to one per twenty sugar units. (Figure 2)

The rate of hydration is controlled primarily by the particle size distribution; whereas, the degree of water gelling or nongelling is controlled by the presence of acetyl groups. Deacetylation of the molecule using a weak base and enhanced by heating, during food processing, allows the formation of thermally-stable gels.



General Properties and Overview

Rapid Hydration

- Nutricol brands of konjac are mechanically processed for improved hydration, allowing konjac to meet the requirements of the food industry's processing methods.
- Konjac swells and hydrates, even at room temperature, to form highly viscous aqueous sols.
- Increasing temperature and shear during hydration greatly speeds full hydration.

Pseudoplastic Viscosifier

- Konjac sols are responsive to varying shear rates.
- Very high shear may be used to reduce the processing viscosity of konjac without affecting the ability to form a gel in subsequent processing steps.

Effect of Temperature

- Sols of konjac are less viscous hot than cold, as with most natural gums.

Gelling Properties

- Heat-stable gels form when set with alkali and heat.
- Gels are acid and salt stable.

Effective at Low Use Levels as a Viscosifier

- Konjac develops higher viscosity than guar gum or locust bean gum at comparable use levels.

Effect of Ionic Environment

- Konjac flour is basically a non-ionic polysaccharide. After the konjac is hydrated, the addition of calcium, potassium or sodium ions does not result in a gel structure, and has little or no effect on viscosity of a 0.5% konjac solution.

Synergisms

- Konjac is synergistic with kappa carrageenan and xanthan gum to form thermally-reversible and/or thermally-stable gels.
- Konjac interacts with starch to greatly increase viscosity to provide unique thermally-stable gels when base is added.

pH Stability

- A 1.0% aqueous solution of konjac is moderately affected by acid. At 122°F (50°C) the solution maintains its viscosity, even at 3.4 pH. At higher process temperatures, 167°F (75°C), the solution viscosity begins to decrease.
- Konjac gels are generally stable at pH levels ranging between 3 and 9.

Nutricol® Konjac

Contents

FMC's Nutricol brand products are based on a unique hydrocolloid called konjac flour. In addition to its inherent gelling and thickening properties, konjac flour is synergistic with certain other hydrocolloids and starches.

Nutricol products are designed to capitalize on this synergy and are formulated to produce the precise

functionality required by individual food products. This brochure provides detailed information on the basic Nutricol products, and properties of konjac when combined with other ingredients.

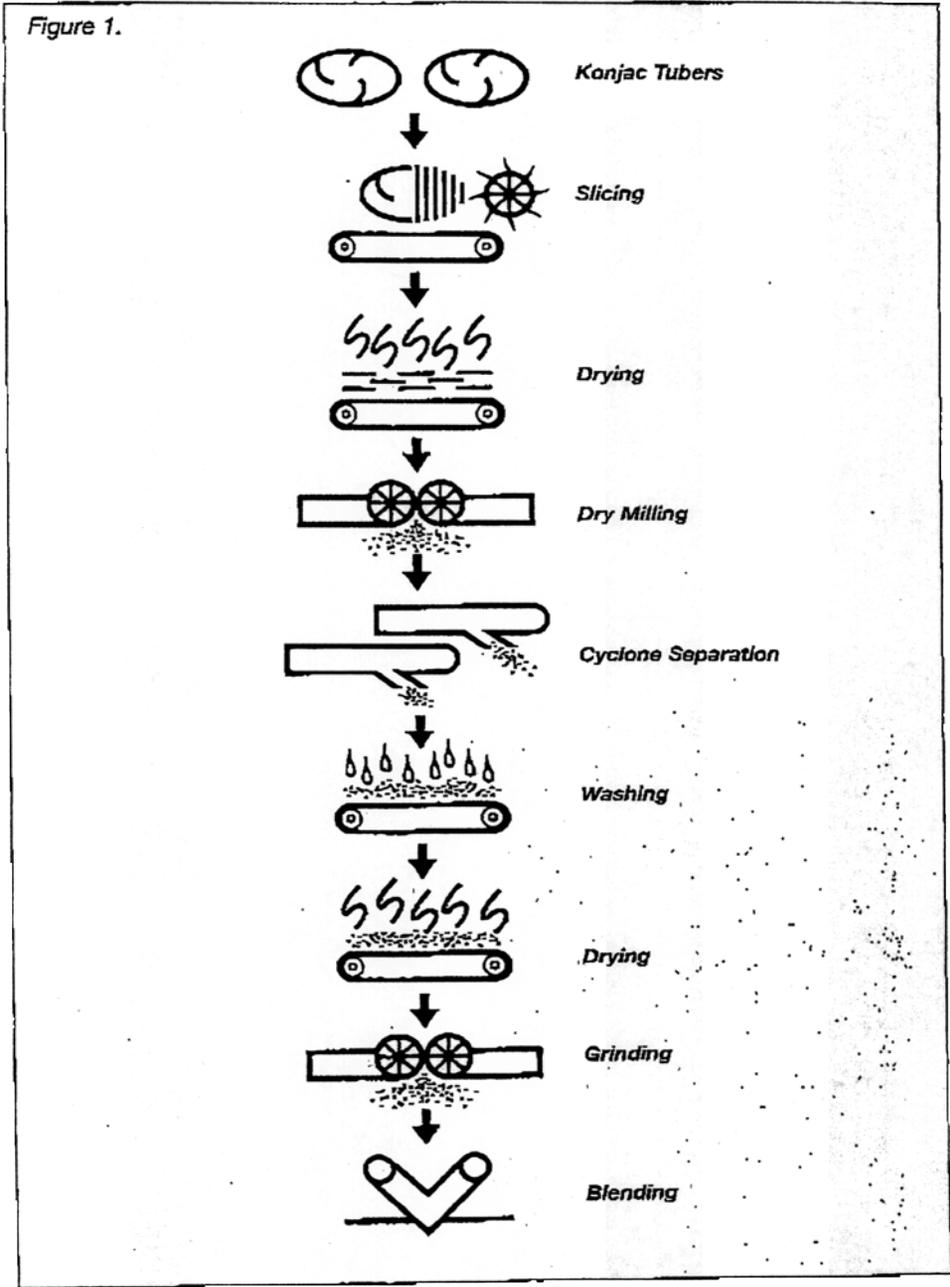
For more detailed information on specific Nutricol products, contact your FMC Food Ingredients Division technical representative.

	Page
Manufacturing	1
Basic Chemistry	2
General Properties and Overview	2
Properties of Konjac Solutions	3
Properties of Konjac Gels	3-5
Regulatory and Labeling	6

Manufacturing

The dried tuber of the konjac plant contains about 30-50% glucomannan gum. Konjac flour is obtained by grinding the dried pieces of the tuber. Konjac flour (70-80% glucomannan) is produced by grinding and separating the glucomannan-containing sacs from the surrounding starchy materials. The purified konjac is subsequently washed and reduced in particle size to improve product performance. The powder is blended by FMC to strict product standards and marketed under the Nutricol trademark. The general manufacturing process for producing Nutricol® konjac is described in Figure 1.

Figure 1.



MATERIAL SAFETY DATA SHEET

KONJAC FLOUR



MSDS Ref. No: 37220-17-0
Version: Global
Date Approved: 06/30/1998
Revision No: 4

This document has been prepared to meet the requirements of the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200; the EU Directive, 91/155/EEC and other regulatory requirements.

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: KONJAC FLOUR

CHEMICAL NAME: Konjac Flour

CHEMICAL FAMILY: Polysaccharides: Sugars

MOLECULAR FORMULA: Konjac Flour: Polysaccharide chain of mannose and glucose in a molar ratio of 1:6:1 with beta 1-4 linkages (glucomannan).

SYNONYM(S): Konjac Flour, Konjac Gum, Yam Flour

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Emergency Telephone Numbers:

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(202) 483-7616 (All other countries)

2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name

Konjac Flour

CAS # EC Class

37220-17- Xi, Xn,
0 R37, R42

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

IMMEDIATE CONCERNS:

- Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.
- Produces oxides of nitrogen and sulfur upon burning.
- Respiratory sensitizer.
- Irritating to the upper respiratory tract at high airborne concentrations.

POTENTIAL HEALTH EFFECTS: Inhalation of dust produces allergic respiratory effects in sensitized individuals, including asthma, coughing, wheezing and shortness of breath. Symptoms may occur immediately, or may be delayed several hours after exposure. Konjac flour is irritating to the upper respiratory tract at high airborne concentrations.

4. FIRST AID MEASURES

EYES: Flush with plenty of water. Get medical attention if irritation occurs and persists.

SKIN: Wash with plenty of soap and water. Get medical attention if irritation occurs and persists.

INGESTION: Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

INHALATION: Remove to fresh air. If breathing difficulty or discomfort occurs and persists, see a medical doctor. If breathing has stopped, give artificial respiration and see a medical doctor immediately.

NOTES TO MEDICAL DOCTOR: Konjac flour has low toxicity and is a generally recognized as safe (GRAS) substance. Treatment for asthma should be considered if respiratory distress is present, otherwise treatment is symptomatic and supportive.

5. FIRE FIGHTING MEASURES

FLASH POINT AND METHOD: Not applicable

FLAMMABLE LIMITS: Not applicable

AUTOIGNITION TEMPERATURE: Not applicable

EXTINGUISHING MEDIA: Water, CO2

EXPLOSION HAZARDS: The accumulation of excessive dust on overhead structures may produce explosive concentrations when disturbed and dispersed by a small explosion that shakes down accumulated dust and causes, momentarily, a flammable concentration.

FIRE FIGHTING PROCEDURES: For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of

combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.

HAZARDOUS DECOMPOSITION PRODUCTS: Will produce oxides of nitrogen and sulfur upon burning.

6. ACCIDENTAL RELEASE MEASURES

RELEASE NOTES: Maintain good housekeeping practices to minimize accumulation of settled dust, especially on overhead surfaces. Sweep up the spilled material and dispose of in accordance with the waste disposal method outlined in Section 13, "Disposal Considerations" below.

7. HANDLING AND STORAGE

GENERAL PROCEDURES: Use local exhaust or general dilution ventilation to control exposure to dust. Always use safe lifting techniques when manually moving containers, especially when shipping containers weighing more than 50 pounds (22.7 kg). Exhibits strong marine odor. Open container in well-ventilated area. Store in a dry area for product quality assurance. Pallets should be stacked in a stable manner. Maintain adequate clearance from structural members and sprinklers. NFPA and U.S. OSHA state a minimum of 18 inches (45.7 cm) clearance shall be maintained between the top of storage and the ceiling sprinkler deflectors.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.

RESPIRATORY: Whenever dust, in the worker's breathing zone, cannot be controlled with ventilation, workers should wear respirators which are approved for protection against airborne dust (by U.S. NIOSH/MSHA, EU CEN or comparable certification organization).

PROTECTIVE CLOTHING: Not normally required.

GLOVES:
Not required.

EXPOSURE LIMITS:
None established.

9. PHYSICAL AND CHEMICAL PROPERTIES

ODOR: Strong, marine

KONJAC FLOUR

Page 4 of 7

APPEARANCE: Dry powder

pH: (In solution) 6.0 - 11.0

PERCENT VOLATILE: Not applicable

VAPOR PRESSURE: Not applicable

VAPOR DENSITY: (Air = 1) Not applicable

BOILING POINT: Not applicable

MELTING POINT: Not applicable

SOLUBILITY IN WATER: (% by weight) 7 - 10%

EVAPORATION RATE: (Butyl Acetate = 1) Not applicable

SPECIFIC GRAVITY: (H₂O = 1) Approximately 1 g/cc

COEFF. OIL/WATER: (K_{ow}) Not applicable

OXIDIZING PROPERTIES: Not applicable

COMMENTS:

EXPLOSIVE PROPERTIES : Not applicable

FAT SOLUBILITY : Not applicable

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID: None known

STABILITY: Non-reactive

HAZARDOUS DECOMPOSITION PRODUCTS: Remote possibility of ignition which may release oxides of nitrogen and sulfur.

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: Non-irritating (rabbit) [FMC Study Number I93-1778]

SKIN EFFECTS: Non-irritating (rabbit) [FMC Study Number I93-1776]
Primary Irritation Index = 0/8.0

DERMAL LD₅₀: >2000 mg/kg (rat) [FMC Study Number I93-1777]

ORAL LD₅₀: >5000 mg/kg (rat) [FMC Study Number I93-1775]

INHALATION LC₅₀: >0.64 mg/L/4 hr (maximum attainable concentration, no mortalities) [FMC Study Number I93-1779]

SENSITIZATION: (Skin) Non-sensitizing (guinea pig) [FMC Study Number I93-1774]

ACUTE EFFECTS FROM OVEREXPOSURE: Inhalation of dust produces allergic respiratory effects in sensitized individuals, including asthma, coughing, wheezing and shortness of breath. Symptoms may occur immediately, or may be delayed several hours after exposure. Konjac flour was not toxic when tested by oral or dermal routes of exposure. Konjac flour is irritating to the upper respiratory tract at high airborne concentrations.

CHRONIC EFFECTS FROM OVEREXPOSURE: Data on oral human studies indicate no adverse reactions or toxic effects with konjac flour (Lancet, 1[8123], 987-88, 1979). Konjac flour was not mutagenic in an Ames test [FMC Study Number I93-1780], or in the mouse lymphoma assay [FMC Study Number I95-1979]. It did not cause chromosome damage in mouse bone marrow [FMC Study Number I95-1980]. Konjac has been evaluated by the 1993 JECFA (Joint WHO/FAO Expert Committee on Food Additives) and assigned a temporary ADI (Acceptable Daily Intake) of "not specified". Konjac is considered a generally recognized as safe (GRAS) substance by the U.S. Food and Drug Administration.

CARCINOGENICITY:

IARC: Not listed

NTP: Not listed

OSHA: Not listed

OTHER: (ACGIH) Not listed

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: No data available.

ECOTOXICOLOGICAL INFORMATION: No data available.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHOD: No special disposal methods are suggested. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations and standards.

14. TRANSPORT INFORMATION

COMMENTS:

U.S. Dot : Not listed in Title 49 of the U.S. Code of Federal Regulations as a hazardous material.

Shipping Name : National Motor Freight Classification Item 718120, Stabilizer/Emulsifier, Water soluble.

UN (IMO/TMDG) : Not applicable

MARPOL Designation : None

Canada (TDG) : Not applicable

15. REGULATORY INFORMATION

UNITED STATES**SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)**

311 HAZARD CATEGORIES (40 CFR 370): Immediate (acute) health hazard.

SECTION 313 REPORTABLE INGREDIENTS (40 CFR 372): This product does not contain any toxic chemicals subject to the reporting requirements of Section 313, Title III of the SARA (Superfund Amendments and Reauthorization Act) of 1986.

TSCA (TOXIC SUBSTANCE CONTROL ACT)

TSCA REGULATORY (40 CFR 707.60): Not listed

STATE REGULATIONS

PROPOSITION 65 STATEMENT: To the best of our knowledge, this product does not contain any chemicals currently on the California's list of known carcinogens and reproductive toxins.

CANADA

WHMIS (WORKER HAZARDOUS MATERIALS INFORMATION SYSTEM):
Not applicable.

GENERAL COMMENTS:

EU NO. : Not available

EU EINECS NO.
konjac 253-404-6

EU Symbols : Xn, Xi
EU Risk Phrases : R37, R42

EU Safety Advise Phrases : S22, S38

COMMENTS: Contains sulfites due to heat processing. Konjac flour meets the standards set forth in the Food Chemical Codex. Konjac is generally recognized as safe (GRAS) by qualified experts and is in accordance with U.S. Food and Drug Regulations.

16. OTHER INFORMATION

NFPA RATING

HEALTH:	1
FLAMMABILITY	1
REACTIVITY:	0
SPECIAL:	None

Prepared by: FMC Corporation

Section(s) Revised : New Format

NFPA - Degree of Hazard Code:

4 = Extreme

3 = High

2 = Moderate

1 = Slight

0 = Insignificant

NFPA = National Fire Protection Association