



Grain Processing Corporation
1600 Oregon Street • Muscatine, Iowa 52761-1494 USA
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Customer Questionnaire Response for Maltrin®

Grain Processing Corporation Overview for Customer Review

GPC
1600 Oregon St.
Muscatine, Iowa
52761

GPC
1443 S. 300 W.
Washington, Indiana
47501

Corporate Phone Number: 563-264-4847
Website: www.grainprocessing.com

Customer Questionnaire Response for Maltrin®

Section 1: General Information

Section 2: Quality

Section 3: Manufacturing

Section 4: Product Lot Identification and Traceability

Section 5: Pest Control

Section 6: Security

Section 1--General Information

1. Ownership/history of Grain Process Corporation GPC

Grain Processing Corporation (GPC) is a privately owned company. It is a subsidiary of Muscatine Foods Corporation and was established in 1943. It is a corn processing company that makes value-added, environmentally friendly products from renewable resources. The second facility at Washington, IN was built in 1999. The corporate headquarters are located in Muscatine, IA.

2. Property

GPC Muscatine is located on approximately 160 acres in an urban setting at Muscatine, IA. GPC Washington is located on approximately 125 acres in a rural setting at Washington, IN. Both production areas are constructed with concrete floors and walls, all of which are painted or sealed. The exterior area around buildings is paved or gravel and is well maintained.

3. Products Produced

GPC produces the following products: Maltodextrins & Corn Syrup Solids, Industrial & Food Grade Starch, Industrial & Beverage Alcohol, Feed Recovery Products and a variety of other value added products.

4. Registrations or Certifications

- A. FDA #1910695
- B. FDA Bioterrorism Act of 2002
- C. Maltrin® and Corn Syrup Solids Drug Master File #7437
- D. Federal Employer ID # 42-1321075
- E. Standard Industrial Code 2000 (Covering Manufacturing of Food Products)
- F. TTB Certified Quality Control Laboratory
- G. State Certified Biochemical Oxygen Demand (BOD)/Environmental Laboratory

5. FDA Visits

The last time Maltrin was inspected by the FDA at GPC Muscatine was May 20, 2009. No 483s were issued. The FDA has not been to GPC Washington at this time.

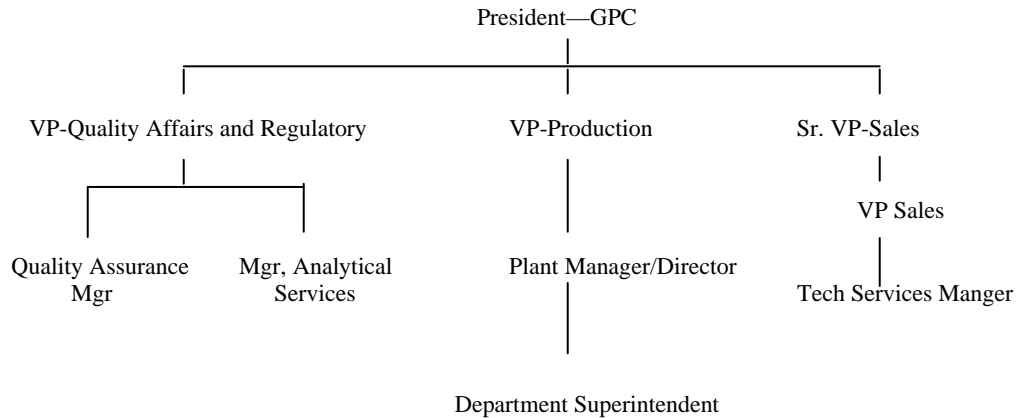
6. Contacts

Technical Service Manager	Angie Eads
Sales Administrator	Tracey Reynolds
GPC Muscatine Production Superintendent	Kevin Lester

GPC Washington Production Superintendent	Jason Fry
GPC Muscatine Analytical Services Manager	Cindy Sparks
GPC Washington Quality Control Manager	Melea Kluemper
GPC Muscatine Quality Assurance Coordinator – Maltrin®	Deb Doehrmann
GPC Washington Quality Assurance Coordinator – Maltrin®	Elizabeth Reed
Quality Assurance Manager	Carla (Casey) Hilton
Environmental Monitoring	Mick Durham

7. Reporting structure

General Organization Chart showing division of Quality, Production, and Sales/Tech Service at GRAIN PROCESSING CORPORATION



8. Work Force

GPC I has a union hourly work force. They are represented by the United Food & Commercial Worker’s International Union of America, AFL-CIO/CIC, Local #86D. GPC II does not have a union work force. Both plants have two 12-hour shifts per day for 365 days per year.

Section 2--Quality

1. Total Quality Management

We have a Quality system designed and verified to meet Good Manufacturing Practices (GMPs). We have a Quality Manual, which is reviewed on a minimum of every five years. There is a Quality SOP manual that is reviewed on a minimum of every three years. In addition, each department has a complete Standard Operating Procedure (SOP) manual for their area. These manuals are available for viewing during a customer audit or visit. We also have training records available. We perform statistical analysis on a monthly basis. QA conducts monthly sanitation/housekeeping inspections and internal audits of the Analytical Services (QC) laboratory and production areas yearly. GPC has a third party audit done by FPA for our Maltrin®, Food and Pharmaceutical grade Starches, and Ethyl Alcohol

Divisions. To view results of a specific audit, please contact your sales representative.

2. ISO 9000 Certification

All written policies, procedures, and documents are written in ISO format. Although we have not chosen to pursue ISO certification at this time, we continue to review and update our system to use ISO standards where appropriate.

3. Records

- A. All quality testing records are kept for a minimum of five years.
- B. We have a Laboratory Information Management System (LIMS) which notifies production and Analytical Services (QC) of sampling and testing needs that are to be done for all in-process and final products. Production has immediate access to the LIMS information through a computer system that is located throughout the Plant and in the Analytical Services (QC) laboratory.
- C. The latest customer specification is kept in the LIMS with a hard copy kept on file with our sales department.

4. Audits & Sanitation Inspections.

- A. The Quality Assurance (QA) Inspectors do sanitation inspections on a monthly basis.
- B. Annual internal audits are done by QA for each Production area and the Analytical Services (QC) laboratory.
- C. Maltrin has a Food Processors Association (FPA) SAFE audit done a minimum of every 14 months. For details, please contract your sales representative.
- D. We have several customer audits and/or visits on a yearly basis.
- E. We audit suppliers of critical ingredients.

5. Laboratory

- A. Both GPC Muscatine and GPC Washington have their own laboratory facility on site. There is an intra-lab check program set up between the laboratories. They each have an AACC check program for their Feeds and Microbiology labs. Both laboratories are TTB (formerly BATF) certified.
- B. Laboratory calibrations are maintained in the LIMS. Methods are formally written and pass through a review committee. Existing methods are reviewed on a three-year basis. Methods may be derived from the Bacteriological Analytical Manual (BAM), Corn Refinery Association (CRA), Association of Official Analytical Chemists (AOAC), United States Pharmacopoeia (USP), American Association of Cereal Chemists (AACC), American Standards of Testing Methods (ASTM), or Corn Industries Research Foundation.

6. Finished product testing and retained samples

- A. Analytical and microbial testing is performed by the Analytical Methods (QC) laboratory on all finished product lots. A second technician verifies all final product test results. Retained samples for each Maltrin® lot are maintained for two years.
- B. Grain Processing Corporation will test for the indicated organisms in the individual monograph for all products produced and marketed under the Pharmacopeia. Due to the difficult task of determining all applications where our products may be used, our customers must communicate any relevant objectionable microorganisms required. Currently our products are tested for the following specific microorganisms *Escherichia coli*, *Salmonella*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Listeria monocytogenes*. In addition to the above-mentioned specific organisms, aerobic plate count (APC), Yeast, Mold, mesophilic plate count and Enterobacteriaceae count are screened.
- C. Any specifications different from or not listed on the product bulletin must be agreed upon between the customer and Grain Processing Corporation during specification approval.

7. Product Release

GPC has standard product specifications. If a customer does not have a unique customer specification, they will be assigned the standard product specifications. If a customer specification differs from the standard, and GPC has agreed to the specification, the specification is built into the LIMS database. In either case, the specification is linked to the customer in our LIMS database. Quality Assurance will release lots based on the conformance of the test data to the customer specification. This is done by the LIMS using the lot selection application and the 'First In, First Out' (FIFO) system. Certificates of Analysis (COA) are also unique to each customer and are linked to the customer/item specification. We can provide COAs on each lot shipped if requested. Products are released for shipment by QA only after all analyses are completed and verified.

8. Corrective Action

Documentation for Correction Action and Customer Complaints is in the Quality Manual and will be available for viewing during a customer visit or audit. If a customer contacts GPC with a complaint or nonconformance, the customer service representative or Salesperson determines the nature and extent of the nonconformance and the lot number(s) involved. A Customer Complaint form is begun for the nonconformance and copies are sent to the Quality, Production and Traffic departments. They will work to determine the cause of the nonconformance and the corrective measures taken to prevent the nonconformance from occurring again. In all cases, the Customer Complaint form will be completed by the appropriate departments and the normal distribution will be given to the complaint. The Senior Vice President of Operations will ensure that the appropriate corrective action has been implemented and is functioning effectively. Quarterly the complaints are

summarily complied through out the year and summaries are sent to all upper management.

9. Notification of Change

GPC will notify the customer of any change that may compromise the food safety, quality, consistency, or agreed upon specification of a finished product.

10. Allergens

GPC MALTRIN® products are processed from dent corn and are not considered an allergen. They do not contain celery; egg product; dairy products/lactose; peanuts, soybeans, nuts, seeds, tree nuts and their oils/extracts; wheat/gluten; seafood; antibiotics; colors; animal fats and oils; monosodium glutamate; tartrazine or cottonseed flour. MALTRIN® products are processed from corn starch on dedicated equipment. We contact all our suppliers and have them fill out a questionnaire to ensure none of these allergens are contained in ingredients we use in our process. SO₂, a sensitizer may be present but, if so, at levels < 10 ppm.

Section 3--Manufacturing

1. GMP Training of Personnel

New employees are trained on Safety, GMPs, HACCP, Right to Know, and Food-Grade handling procedures along with a variety of other training which includes safety and On-The-Job training. The Safety, GMPs, HACCP, Right to Know, and Food-Grade handling procedures are reviewed annually with all employees. All training is documented and kept on file for the length of that person's employment. On-the-job training is verified through a testing process.

2. Hazard Analysis Critical Control Points (HACCP)

- A. A HACCP team has evaluated the Maltrin® process and developed an effective HACCP flow diagram and chart. The team, which consists of Quality, Purchasing, Maintenance, and Production personnel meet at least annually to review the progress for any updates. The team is facilitated by the QA Coordinator for that product type.
- B. The QA HACCP facilitator has had outside HACCP training.
- C. Production and Analytical Services (QC) conduct annual HACCP training to their personnel.
- D. The HACCP program is audited annually as part of the annual internal audit. There are also quarterly checks in place.

3. Raw Material Suppliers/Testing

- A. There is an approved supplier list and program in place. Raw materials may be accepted based on COA, COC or testing, depending on the nature of the

ingredient. Supplier approval involves a supplier questionnaire returned, supplier approval of GPC specifications, and a possible audit.

B. In house raw material testing is done for critical ingredients.

4. Process

A. The MALTRIN® process is a continuous process. It is an enclosed system.

B. GPC Muscatine uses only city water. GPC Washington uses well water that has been validated to meet potable standards. Daily microbial monitoring on water is done. Yearly analytical testing is done. Backflow preventors are in place.

C. Drier air is double filtered and meets or exceeds ASHRAE 3A standards for spray driers.

D. All steam additives are GRAS.

5. Equipment Maintenance

A. Production equipment is on a Preventive Maintenance Program, which is automated through a computer program with our Maintenance Department.

B. All maintenance and calibration schedules are listed in Production SOP Manuals and are available for viewing during a customer audit or visit. The timing of the maintenance and calibration of various equipment has been determined by a set time or hours used, depending on experience of use and/or the manufacturer recommendations.

6. Cleaning Procedures/instructions

A. Procedures/instructions are listed in Production SOP Manuals and are available for viewing during a customer audit or visit. Only hot water is used in cleaning, no chemicals.

B. There is an environmental monitoring program in place that checks for Salmonella and Enterobacteriaceae.

7. Contamination Control

A. Sifters—Located prior to the rare earth magnets, they are 8-mesh stainless steel. At GPC Muscatine they are checked every 8 hours. At GPC Washington they are checked every 6 hours.

B. Rare earth magnets—Bagging lines #1 & #2 go through the rare earth magnets before packaging. The Super Sack line has a double rare earth magnet system. At GPC Muscatine they are cleaned and findings inspected two times per shift while in use. At GPC Washington they are cleaned and findings inspected every 6 hours. Pull tests are done yearly.

C. Metal Detector—The metal detector is located after the bagging unit. It is a Safeline and has a visual and audio alarm system. There are three test cards; a 2.5 mm ferrous, a 3.0 mm nonferrous, and a 3.2 mm stainless steel. Metal detectors

are checked every 8 hours at GPC Muscatine and every 6 hours at GPC Washington. Both locations have a contract with an outside company to service the metal detectors on a routine basis.

- D. If any of the above checks fail inspection, bagging is stopped and an investigation occurs to identify the source. If it can not be identified and accounted for, the material is destroyed back to the last good check.
- E. There is a “No Glass” policy in production.

8. Bagging Scales

They are calibrated at the beginning of each shift with approved weights and an outside contractor calibrates them once per month.

9. Packaging

- A. For 50 pound bags, each bag is shrink wrapped and the pallet is stretched.
- B. Only new, hard wood pallets are used. Pallets are heated treated for insect control.
- C. Slip sheets are used between the pallet and the product bags or totes.

10. Segregation of Non-conforming Product

If a finished product does not meet customer requirements, the material is tagged as reject and moved to an area pending appropriate disposition. No Maltrin® is reworked.

11. Outside Warehouse/Shipping

At our GPC warehouse locations we have limited storage space. We contract storage space with an outside warehouse, with whom we have had a long and successful working relationship. They store GPC product in only food grade warehouses and are audited on a regular basis. For shipping, we work with a select number of carriers who are aware of our requirements or with customer trucks. Shipping conveyances are inspected prior to loading using a check off list. The list contains a preloading inspection as well as a postloading inspection. Both must be completed and signed. They are then sent to QA.

Section 4--Product Lot Identification and Traceability

1. Product Traceability

- A. Traceability of a finished lot to customers is tracked in the LIMS. There are written procedures for performing a pull back of nonconforming material.
- B. Maltrin production is a continuous process. Process traceability to finished lots is available, as the product is stored in bins prior to bagging. The filling of these bins can be traced to the date of production.

C. GPC is registered with the FDA for the Bioterrorism Act of 2002 and can do complete traceability of product from raw ingredients and supplier to finished product and customer.

2. Lot Numbering

Finished lots are coded as shown: M08012201. The first alpha letter is the product, M = Maltrin®; the first two numbers are the year, 08 = 2008; the next three numbers are the Julian date, 122 = May 1; the next two numbers are the lot of the day, 01 = first lot of day. Additional coding may be included in the numbering for internal use.

3. Recall Program

- A. GPC has a recall procedure in place that follows FDA guidelines. A recall team has been identified and individuals' contact information is in the SOP.
- B. Mock recalls are done annually and may involve a single lot to all customers, multiple lots based on ingredient, or multiple lots based on bag products. Effectiveness of the mock recall is documented in terms of time of exercise and % recovery.

Section 5--Pest Control

1. Licensed Pest Control Company

We contract with an outside Licensed Pest Control Company. They have a licensed pest control officer on site five days per week at GPC Muscatine and three days per week at GPC Washington.

2. Pesticide storage

No pesticides are stored on site. All pesticides are food grade approved.

3. Traps

A combination of bait stations outside of buildings and glue boards and/or mechanical traps inside buildings are used. Pheromone traps are also used to monitor insect activity.

Section 6—SAFETY AND SECURITY

1. Work Area

All work areas comply with established safety, regulatory and environmental standards and codes.

2. Measures of Prevention

The proper measures for the prevention of any security related incidents are followed. The following activities are used to accomplish the security level needed to operate within the limits of the QMS:

- Operational Risk Management (ORM)
- 24 hour Guard

- Fenced Perimeter and Camera
- Background checks
- Bioterrorism Threat Action Plan
- Product and ingredient tracking program
- Visitor access control
- Cooperation and collaboration with local, state, and federal authorities (i.e. police, U.S. coast guard, FDA, etc.)
- Audits – internal audits, customer audits, supplier audits
- Employee training

Grain Processing Corporation

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Phone: 563-264-4265 ♦ Fax: 563-264-4289

December 8, 2010


To Whom It May Concern:

MALTRIN® maltodextrins and corn syrup solids and food/pharmaceutical starches have not been irradiated or treated with ethylene oxide at any point of the production process.

If you have any questions regarding this information, please contact me at 563-264-4281, fax 563-264-4289 or via e-mail bahnbob@grainprocessing.com.

Sincerely,

GRAIN PROCESSING CORPORATION



Robert H. Bahn

Marketing Administrator

Food/Pharmaceutical/Personal Care



1600 Oregon Street, Muscatine, IA 52761, USA
grainprocessing.com

April 23, 2013

To Whom It May Concern:

This letter is to state that Grain Processing Corporation is a processor of Yellow Dent Corn to make the following products: Maltodextrins & Corn Syrup Solids, Industrial & Food Grade Starch, Industrial & Beverage Alcohol, Feed Recovery Products and a variety of other value added products.

In the production of our pure Alcohol, GPC does not knowingly add or create any phthalates. This is based on knowledge of the manufacturing process and controlled handling, shipping, and storage of the material and not on actual test data.

If you have any further questions, please feel free to contact us.

Sincerely,

Carla (Casey) Hilton
Director, QA and Compliance
Grain Processing Corporation
E-mail: casey_hilton@grainprocessing.com