



From Field to Family™

June 2024

World Anti-Doping Agency (WADA) Prohibited Substances - Food Starches and MALTRIN®
Maltodextrins and Corn Syrup Solids

Food starches, MALTRIN® maltodextrins and corn syrup solids are produced using corn as the raw material. The process uses starch extracted from the corn kernel to produce food starches, maltodextrins and corn syrup solids. Grain Processing Corporation (GPC) does not use any of the banned substances listed on NSF Annex C, NFL/NFLPA, MLB or the World Anti-Doping Agency (WADA) Prohibited List 2023, which is effective January 1, 2024 through December 31, 2024. This statement is based on processing knowledge and no testing has been conducted on the finished products.

If you have additional questions or concerns, please do not hesitate to contact a representative at Grain Processing Corporation.

Kind regards,

Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
P. 563-264-4735
marcie_hanssen@grainprocessing.com

GPC statements are not to be further edited in verbiage or imagery, and no additional content may be added. Please note the information given in this statement is in relation to products supplied by Grain Processing Corporation and is based upon our interpretation of the relevant legislation. Although offered in good faith, the advice is not legal advice. The labeling substantiation and decision making of all claims for your products is your responsibility. We recommend you consult regulatory and legal advisors prior to making labeling and claim decisions for your products.

This document is valid for one year from the date of issue.



January 2024

To Whom It May Concern:

Regarding Grain Processing Corporation products – Palm Oil is not used as part of our manufacturing process.

If you have any questions regarding this information, please contact me.

Sincerely,

GRAIN PROCESSING CORPORATION

Amber Gregory
Manager, Sales Administration
Grain Processing Corporation
Tel: (563) 264-4285
amber.gregory@grainprocessing.com

GPC statements are not to be further edited in verbiage or imagery, and no additional content may be added. Please note the information given in this statement is in relation to products supplied by Grain Processing Corporation and is based upon our interpretation of the relevant legislation. Although offered in good faith, the advice is not legal advice. The labeling substantiation and decision making of all claims for your products is your responsibility. We recommend you consult regulatory and legal advisors prior to making labeling and claim decisions for your products.



From Field to Family™

April 2023

California Proposition 65 Statement for Food Starches and MALTRIN® Maltodextrins
and Corn Syrup Solids

MALTRIN® maltodextrins and corn syrup solids and food starches manufactured by Grain Processing Corporation do not contain any of the substances listed in California Proposition 65 known to cause cancer or reproductive toxicity (last updated April 21, 2023).

If you have any other questions or problems concerning quality, please feel free to contact Grain Processing Corporation.

Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
P 563.264.4735
F 563.264.4617
marcie_hanssen@grainprocessing.com

January 2023

ELEMENTAL IMPURITIES USP & EP - MALTRIN[®] NF Products


United States Pharmacopeia (USP) replaced the Heavy Metals procedure in General Chapter <231> with the new General Chapters <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. European Pharmacopeia deleted chapter 2.4.8 Heavy Metals from individual monographs and implemented chapter 5.20- Elemental Impurities and chapter 2.4.20 – Determination of Elemental Impurities to align with the guidelines and principles of ICH Q3D. Grain Processing Corporation (GPC) does not knowingly add or create elemental impurities in the manufacturing process of MALTRIN[®] maltodextrin and corn syrup solids products.

Testing has been completed on random lots on a yearly basis. The data from the historical testing indicates the following elemental impurities have not been detected in the finished products: arsenic, cadmium, lead, mercury, chromium, molybdenum, nickel, cobalt, copper, iron, zinc, and aluminum. The compliance statement above regarding the US and European Pharmacopeia Elemental Impurities will be based on knowledge of the manufacturing process and supported by the data obtained from the annual random finished product testing.

Metal catalysts or reagents are not used in the manufacturing process; therefore, the following elemental impurities should not be present: iridium, osmium, palladium, platinum, rhodium, and vanadium. Although no metal catalysts or reagents are used, these impurities have been added to the annual testing protocol for verification. The additional impurities listed above have not been detected.

Please do not hesitate to contact GPC, if additional information or clarification is required.

Kind Regards,



Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
marcie_hanssen@grainprocessing.com

This document is valid for one year from the date of issue.



From Field to Family™

January 2023

To Whom It May Concern:

Re: Aflatoxin Testing

Grain Processing Corporation is in regular communication with the USDA and Iowa State County Board of Extension concerning corn and growing conditions. We have developed a sampling program for detection of aflatoxin and/or mycotoxin contamination of incoming corn.

During typical growing years, we perform black light screening on all shipments and periodic random wet chemistry testing is done for aflatoxin on incoming corn. This is based on historical data collected in past years. If the weather conditions are favorable for aflatoxin production; OR if we see an increase in the number of corn lots with aflatoxin; OR if the USDA/ISCBE issues reports indicating an increase of aflatoxin in corn from areas where GPC purchases corn, we will increase our testing parameters. Any shipment over 19 ppb is rejected and not allowed into the plant (FDA and USDA limits for food products).

Grain Processing Corporation has systems in place for the testing of finished products. If you have any other questions concerning this matter, please feel free to contact us.

Sincerely,

Joseph R. Glenn
Quality Assurance Manager
Grain Processing Corporation



January 2023

To Whom It May Concern:

Re: GPC's Quality Policy for MALTRIN® Products

Grain Processing Corporation (GPC) has instituted the following quality policy parameters regarding our MALTRIN® products:

- All written policies, procedures, and documents follow the ISO format for documentation, although we have not chosen to pursue ISO certification at this time.
- Our Quality system is designed and verified to meet current Good Manufacturing Practices (cGMPs).
- Our company has a detailed Quality Manual, and the MALTRIN® division has complete Standard Operating Procedures (SOP) manuals.
- A HARPC (Hazard Analysis and Risk-Based Preventative Controls) team has been established and reviews the MALTRIN® process for any potential food safety-related risks. This evaluation is completed annually at a minimum.
- The MALTRIN® division undergoes annual GFSI third-party audits by the Brand Reputation through Compliance Global Food Safety Standard (BRCGS).
- The Quality Control laboratory is certified by the TTB (Tax, Tariff, and Trade Bureau) of Alcohol and is state certified as a Biochemical Oxygen Demand (BOD)/Environmental Lab. We conduct internal audits of the QC laboratory and production areas annually.
- Select test methods in our microbiology laboratory are ISO 17025-accredited.

If you have any other questions concerning this matter, please feel free to contact us.

Sincerely,

Joseph R. Glenn
Quality Assurance Manager
Grain Processing Corporation



From Field to Family™

January 2023

TSE/BSE Statement for Food Starches and
MALTRIN® Maltodextrins and Corn Syrup Solids

The statement below is provided to confirm the products manufactured by Grain Processing Corporation comply with guidance on minimizing the risk of TSE/BSE via human and veterinary medicinal products (EMEA/410/01/REV 03).

Grain Processing Corporation's MALTRIN® Maltodextrins, Corn Syrup Solids and Food Grade Starches are not derived from 'TSE/BSE relevant animal species'.

The raw materials and reagents used in the manufacturing process of the products are not derived from 'TSE/BSE relevant species'.

No materials derived from 'TSE/BSE relevant species' come into contact with the product or equipment used in the manufacture.

No gelatin, bovine blood derivatives, or peptones are used in the manufacturing process or come in contact with the equipment used in the manufacture of these products.

Kind Regards,

Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
marcie_hanssen@grainprocessing.com

This document is valid for one year from the date of issue.



January 2023

Gluten-Free Status of Food Starches and
MALTRIN® Maltodextrins and Corn Syrup Solids

According to CODEX ALIMENTARIUS International Food Standards for gluten-free foods, “gluten is defined as a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.” While food starches and MALTRIN® maltodextrins and corn syrup solids do contain a small amount of protein, they are derived from corn starch and per this definition would be considered gluten-free. In addition, no enzymes derived from any of the gluten containing grains are used nor is gluten from wheat, rye, barley, oats or their crossbred varieties added to the product during or following processing. None of the gluten containing grains, including wheat, rye, barley, oats or their crossbred varieties are stored or processed at this facility including any common equipment used to produce maltodextrins, corn syrup solids or food starches; therefore testing for cross-contact contamination is not relevant.

If you have any questions concerning quality, please feel free to contact GPC.

Kind regards,

A handwritten signature in cursive script that reads 'Marcie A. Hanssen'.

Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
P. 563-264-4735
marcie_hanssen@grainprocessing.com

This document is valid for one year from the date of issue.



From Field to Family[™]

January 2023

Heavy Metal Statement for MALTRIN[®] Maltodextrins

Grain Processing Corporation (GPC) is a processor of yellow dent corn to make the following products: MALTRIN[®] maltodextrins. GPC does not knowingly add heavy metals (including lead, mercury, arsenic and cadmium) in the manufacture of these products. Testing is done on random lots on a yearly basis. The historical testing indicates these products will meet inorganic impurities of NMT 0.5 ppm of lead outlined in Food Chemical Codex (FCC) for maltodextrins.

Please do not hesitate to contact GPC, if you need additional information.

Kind regards,

Marcie Hanssen
Quality & Regulatory Specialist
Grain Processing Corporation
P. 563-264-4735
marcie_hanssen@grainprocessing.com

This document is valid for one year from the date of issue.



January 2023

To Whom It May Concern:

You have asked about the presence of residual solvents in Grain Processing Corporation's MALTRIN® products. The only solvent used in manufacturing MALTRIN® products is water. **No other solvents are present**, including the residual solvents listed by the USP Chapter <467> shown below.

<u>Class</u>	<u>Quantity</u>
Class 1	None Present
Class 2	None Present
Class 3	None Present
Other Residual Solvents (table 4)	None Present

This is based on knowledge of the manufacturing process and controlled handling, shipping, and storage of the material. There is no potential for specific toxic solvents to be present and the material, if tested, will comply with established standards.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Glenn', is written over a white background.

Joseph R. Glenn
Quality Assurance Manager
Grain Processing Corporation



From Field to Family™

January 2023

To Whom It May Concern:

The country of origin for MALTRIN® maltodextrins and corn syrup solids and food starches is the USA. All raw material used in processing is also of USA origin.

If you have any questions regarding this information, please contact me.

Sincerely,

GRAIN PROCESSING CORPORATION

Amber Gregory
Manager, Sales Administration
Grain Processing Corporation
Tel: 563-264-4285
amber.gregory@grainprocessing.com



From Field to Family[™]

January 2023

To Whom It May Concern:

Grain Processing Corporation's products are derived from the corn kernels of #2 Yellow Dent Corn – *Zea mays* var. *indentata*.

If you have any questions regarding this information, please contact me.

Sincerely,

GRAIN PROCESSING CORPORATION

Amber Gregory
Manager, Sales Administration
Grain Processing Corporation
Tel: 563-264-4285
amber.gregory@grainprocessing.com



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

Date: April 24, 2020

To: Valued Customers of Grain Processing Corporation

From: Tim Prichard
Director of Quality and Regulatory Affairs
Grain Processing Corporation

Subject: Nitrosamine Risk Assessment for Excipients
MALTRIN[®] Maltodextrin

Grain Processing Corporation (GPC) has assembled a team of chemistry and process resources to evaluate and assess our MALTRIN[®] process inputs and processing steps, with regard to the risk of presence of, or development of nitrosamine impurities. The eight nitrosamine impurities of concern are NDEA, NDMA, NMBA, NMEA, NIEA, NDIA, NDBA and NDPA.

GPC has adopted the IPEC Europe standard format that was developed with reference to EMA requirements. The use of this standard format will facilitate data collection from excipient suppliers and provide more efficient process conducting the required risk assessment activities by drug product manufacturers / Marketing Authorization Holders (MAH).


The information contained in the questionnaire outlined below is believed to be accurate to the best of our knowledge and belief. Please feel free to contact me via my contact information below if you have any questions.

Thank You,

Tim Prichard
Director of Quality and Regulatory Affairs
Email: tim.prichard@grainprocessing.com
Office: 563-264-4666
Cell: 563-594-9715



This risk assessment has been prepared for:

Product Name and Item Numbers:	MALTRIN [®] Maltodextrins- All items
Prepared By:	The information contained in the risk assessment below is believed to be true and accurate to the best of our knowledge and belief- Signed:  _____ Date: <u>4/24/2020</u> Tim Prichard, Director of Quality and Regulatory Affairs

Nitrosamine Risk Evaluation Questionnaire:

	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	Information not available <input type="checkbox"/>
1) Is sodium nitrite, or any other nitrite or nitrosating agent: - used in any steps in the manufacturing process as reagents/catalysts?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-known to be used in the preparation of raw materials or intermediates used in the manufacturing process?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-known to be used in the preparation of reagent/catalysts/processing aids used in the manufacturing process?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-known to be generated as impurities during the manufacturing process?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
Other Comments:			



<p>2) Have you analyzed, and are those results available for the excipient for:</p> <p>-Nitrites?</p> <p>-Nitrates?</p> <p>-Nitrosamines?</p> <p>If yes please provide test results, and a general indication of test method applied, and if the testing was in-house or at a contacted laboratory. Comments:</p>	<p>YES <input type="checkbox"/></p> <p>YES <input type="checkbox"/></p> <p>YES <input checked="" type="checkbox"/></p>	<p>NO <input checked="" type="checkbox"/></p> <p>NO <input checked="" type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Test Results if Available</p> <p>See results on page 7</p>
<p>3) If water is used in the manufacturing process, is it prepared by distillation, by ion exchange, or by reverse osmosis?</p> <p>If NO, please indicate the maximum level of:</p> <ul style="list-style-type: none"> - Nitrites - Nitrates as NO₃ / N- <p>Comments: Boiler treatment chemicals have also been assessed in regards to steam and condensate use in our process. Steam line/condensate treatments are free of amines. Treatment chemicals are not carried over into the steam.</p>	<p>YES <input type="checkbox"/></p> <p>MCL (Maximum Contaminant Level)</p> <p>MCL NO₃ 45 mg/L</p> <p>MCL N- 10 mg/L</p> <p>Testing is conducted by the municipal water provider</p> <p>Nitrosamine Screening- city and well water sources- None Detected- See pages 6 & 7</p>	<p>NO <input checked="" type="checkbox"/></p> <p>Not Specified</p> <p><input checked="" type="checkbox"/></p>	<p>Information not applicable</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>



4) Is there any secondary and/or tertiary amine present in the manufacturing process as:			Information not applicable
-Raw Material?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-Intermediate?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-Reagent?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-Processing Aid?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-Catalyst / Base?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
-Solvent?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, are those amines present in the			
-Same	YES <input type="checkbox"/>	NO <input type="checkbox"/>	<input checked="" type="checkbox"/>
-Previous	YES <input type="checkbox"/>	NO <input type="checkbox"/>	<input checked="" type="checkbox"/>
-Subsequent	YES <input type="checkbox"/>	NO <input type="checkbox"/>	<input checked="" type="checkbox"/>
step as any nitrosating agent mentioned in section 1?			
Information about the chemical name / structure of the amine(s):			
Comments:			



<p>5) Is there any amide, primary amine, or ammonium salt used or present in the substance manufacturing process as:</p> <ul style="list-style-type: none">-Raw Material? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>-Intermediate? YES <input type="checkbox"/> NO <input type="checkbox"/>-Reagent? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>-Processing Aid? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>-Catalyst / Base? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>-Solvent? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>-Washing Fluid? YES <input type="checkbox"/> NO <input type="checkbox"/> <p>Information about the chemical name / structure:</p> <p>Comments:</p>			<p>Information not applicable</p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p>
<p>6) Recycled/recovered Solvents:</p> <ul style="list-style-type: none">-Are recycled /recovered nitrogen containing solvents used in the manufacturing process? <p>Comments:</p>	<p>YES <input type="checkbox"/></p>	<p>NO <input checked="" type="checkbox"/></p>	<p>Information not applicable</p> <p><input type="checkbox"/></p>



<p>7) Multipurpose Equipment:</p> <p>-Is the substance produced on multipurpose equipment?</p> <p>-In the case of multipurpose equipment, is the equipment used for manufacturing of any material involving nitrites, nitrosating agents or material identified with a risk of formation of nitrosamines?</p> <p>Comments:</p>	<p>YES <input type="checkbox"/></p> <p>YES <input type="checkbox"/></p>	<p>NO <input checked="" type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Not Applicable</p> <p><input checked="" type="checkbox"/></p>
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Water Testing Results:

Laboratory: Eurofins Eaton Analytical South Bend, IN

Client Name: Grain Processing Corporation

Report #: 482299

Sampling Point: Well Water

PWS ID: Not Supplied

Semi-volatile Organic Chemicals									
Analyte ID #	Analyte	Method	Reg Limit	MRL†	Result	Units	Preparation Date	Analyzed	EEA ID #
924-16-3	N-Nitrosodi-N-butylamine (NDBA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
621-64-7	N-Nitrosodi-N-propylamine (NDPA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
55-18-5	N-Nitrosodiethylamine (NDEA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
62-75-9	N-Nitrosodimethylamine (NDMA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
86-30-6	N-Nitrosodiphenylamine (NDPhA)	521	---	20	< 20	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
10595-95-6	N-Nitrosomethylethylamine (NMEA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
59-89-2	N-Nitrosomorpholine (NMOR)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
100-75-4	N-Nitrosopiperidine (NPIP)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727
930-55-2	N-Nitrosopyrrolidine (NPYR)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 15:39	4599727



Sampling Point: City Water

PWS ID: Not Supplied

Semi-volatile Organic Chemicals									
Analyte ID #	Analyte	Method	Reg Limit	MRL†	Result	Units	Preparation Date	Analyzed	EEA ID #
924-16-3	N-Nitrosodi-N-butylamine (NDBA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
621-64-7	N-Nitrosodi-N-propylamine (NDPA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
55-18-5	N-Nitrosodiethylamine (NDEA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
62-75-9	N-Nitrosodimethylamine (NDMA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
86-30-6	N-Nitrosodiphenylamine (NDPhA)	521	---	20	< 20	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
10595-95-6	N-Nitrosomethylethylamine (NMEA)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
59-89-2	N-Nitrosomorpholine (NMOR)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
100-75-4	N-Nitrosopiperidine (NPIP)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728
930-55-2	N-Nitrosopyrrolidine (NPYR)	521	---	2.0	< 2.0	ng/L	04/14/20 07:55	04/21/20 16:01	4599728

† EEA has demonstrated it can achieve these report limits in reagent water, but can not document them in all sample matrices.

Reg Limit Type:	MCL	SMCL	AL
Symbol:	*	^	‡

MALTRIN® Testing Results:

Laboratory: Eurofins New Orleans, LA

Sample Description MALTRIN MALTODEXTRIN
Client Sample Code 1B000249611
Sample Reference M100

Reception Date 02/17/2020
Reception Temperature 25 (Celsius)
Sample Condition Acceptable
Purchase Order P100067130

Test Results

QA25V - Nitrosamines (Foods, GC-MSMS)
Completion Date: 02/20/2020 **Method:**

N-Nitrosodimethylamine (NDMA)	<0.50 µg/kg
N-Nitrosomethylethylamine (NMEA)	<2.00 µg/kg
N-Nitrosodiethylamine (NDEA)	<2.00 µg/kg
N-Nitrosodipropylamine (NDPA)	<2.00 µg/kg
N-Nitrosopyrrolidine (NPYR)	<2.00 µg/kg
N-Nitrosomorpholine (NMOR)	<2.00 µg/kg
N-Nitrosopiperidine (NPIP)	<2.00 µg/kg
N-Nitrosodibutylamine (NDBA)	<2.00 µg/kg
N-Nitrosodiphenylamine (NDPhA)	<2.00 µg/kg

Result