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[grainprocessing.com](http://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<sup>®</sup> Maltodextrin

Grain Processing Corporation (GPC) has assembled a team of chemistry and process resources to evaluate and assess our MALTRIN<sup>®</sup> 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](mailto:tim.prichard@grainprocessing.com)  
Office: 563-264-4666  
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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:			





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> <p>-Raw Material?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input checked="" type="checkbox"/></p> <p>-Intermediate?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input type="checkbox"/></p> <p>-Reagent?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input checked="" type="checkbox"/></p> <p>-Processing Aid?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input checked="" type="checkbox"/></p> <p>-Catalyst / Base?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input checked="" type="checkbox"/></p> <p>-Solvent?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input checked="" type="checkbox"/></p> <p>-Washing Fluid?                      <b>YES</b> <input type="checkbox"/>                      <b>NO</b> <input type="checkbox"/></p> <p>Information about the chemical name / structure:</p> <p>Comments:</p>			<p><b>Information not applicable</b></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> <p>-Are recycled /recovered nitrogen containing solvents used in the manufacturing process?</p> <p>Comments:</p>	<p><b>YES</b> <input type="checkbox"/></p>	<p><b>NO</b> <input checked="" type="checkbox"/></p>	<p><b>Information not applicable</b></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><b>Not Applicable</b></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**