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Solutions

2020 **USG Feed Grade** Survey Guide – Detroit

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CONTENTS

USG FEED GRADE PRODUCTS

1. USG Calcium Sulfate Feed Grade - Regular
2. USG Calcium Sulfate Feed Grade - Coarse

The following documents can be found on usg.com:

- Memo of Insurance
- NAFTA Certificate of Origin
- Product Specification Sheet
- SDS Sheet for Each Product
- Kosher Certificate
- Process Flow Chart
- OMRI Certificate

PLANT ADDRESS INFORMATION:

Site Name: United States Gypsum Company Detroit Plant 891

Address: 10090 West Jefferson Ave. River Rouge, MI 48218

Phone: 313-624-4245 FAX:

KEY CONTACTS:

Quality Supervisor: John Kempton

Phone: 313-624-4278 Email: jkempton@usg.com

Production Manager: Caitlin Boote

Phone: 313-624-4236 Email: cboote@usg.com

Plant Manager: Matthew Craig

Phone: 313-624-4230 Email: mcraig@usg.com

Customer Service Center:

Phone: 800-621-9523 Email: spdcustomerserviceteam@usg.com

1.0 GENERAL INFORMATION

- Is your company: Private: X Public: Union: Union Name:
- Number of years in business: 118 years
- How many shifts are in operation? 1 shift for Mill operations and 3 shifts for Durock operations
- Is your facility registered under the FDA Bioterrorism Registration program? Yes X No
- If so what is the FDA Bioterrorism Registration Number? 17632056962
- Can you provide a Certificate of Analysis on every lot of product supplied? Yes X No

2.0 FEED GRADE SAFETY

- Do you have an operational HACCP plan for your products? Yes X No
- Have you implemented a documented GMP program? Yes No X
- Have you implemented a documented sanitation program? Yes No X
- Do you have a food defense program? Yes No X
- Does the facility have a Glass, Ceramics and Brittle Plastics Control Policy or Program to prevent contamination from above sources within the product? Yes No X
- Do you have a pest control program in place? Yes X No

  IF YES, provide name of contracting service: Rose pest control
- Do you have controls in place to prevent cross-contamination? Yes X No

  IF YES, describe (e.g. separate air handling systems, separate suites or buildings, etc.):

  The plant has designated manufacturing systems and storage bins
- Do you conduct a 3rd party audit of your food safety systems? Yes No X

  IF YES, name of 3rd party auditors:

  Date of last audit: (month/day/year)
- Are there provisions for power backup sources for critical systems if main power should fail? Yes No X
- Please complete the following for foreign material control devices.

	Yes	No	Type/size and Location
Device In-line?	X		1 metal detector and 2 magnets
Magnets?	X		2 magnets on silo incline belt
Screens/sieve?	X		2 hummer screens
Filters?		X	
Metal Detector?	X		1 metal detector on silo incline belt

SENSITIVITY 3 mm: Ferrous X Non-Ferrous X Stainless X

3.0 QUALITY CERTIFICATION

- Do you have an on-site laboratory? Yes [X] No [ ]

IF YES, what certification? None

4.0 QUALITY SYSTEM STATUS

- Do you have a company Quality Manual? Yes [X] No [ ]
- Does your company have a statement of its quality policy? Yes [X] No [ ]
- Do you have an employee-training Program? Yes [X] No [ ]
- Do you document training for all employees? Yes [X] No [ ]
- Do you perform periodic quality system audits to ensure compliance? Yes [X] No [ ]

IF YES, frequency: Yearly

Date of last audit: 2018

- Do you have a formal customer complaint system with effective follow-up corrective action procedures? Yes [X] No [ ]

IF YES, name of 3rd party auditors: FDA

Date of last audit: (month/day/year) 6/25/12

- Does a supplier evaluation exist for packaging, pallets and bags? Yes [X] No [ ]
- Are supplies/products obtained only from currently approved suppliers? Yes [X] No [ ]
- Do you have mutually agreed upon specifications with your suppliers? Yes [X] No [ ]
- Do you have inspection procedures and/or requirements for the control of incoming materials? Yes [X] No [ ]
- Do you have a specific detailed program to bring about continuous improvements in quality with objectives demonstrated company/plant wide?

Quality Improvement Plan

5.0 TESTING/LABORATORY

- Do you have an on-site laboratory? Yes [X] No [ ]

If your laboratory testing is not done in house, what testing services do you use?

- What monographs does the material(s) comply with?

BP [ ] Ph [ ] Eur [ ] USP [ ] FCC [ ]

Other [X] (Detail)

USG standards

- How many staff in your laboratory? 3
- Are your methods validated? Yes ☐ No X
- Are they available to customers? Yes ☐ No X
- Are there written specifications for raw materials and finished products? Yes X No ☐
- Are they available to customers? Yes X No ☐
- Are retentions kept for
  1. Raw Materials Yes ☐ No X
  2. Finished Product Yes X No ☐
- How long are the retention samples kept? 1 year
- Is your facility compliant with Q3C Impurities: Residual Solvent testing for the subject product?

  Yes ☐ No ☐ N/A X because solvents are not used

  IF YES, attach a copy of results.
- Do you test Heavy Metals? Yes X No ☐
- Do you conduct in-process testing? Yes X No ☐
- Do you test final product for conformance to specifications? Yes X No ☐
- Do you have a written system for disposition of off-specification or questionable product? Yes X No ☐
- Are non-conforming items identified and segregated? Yes X No ☐
- Do you have an implemented Preventative Maintenance program? Yes X No ☐
- Is test equipment calibrated and are results documented? Yes X No ☐

6.0 EQUIPMENT

- Is equipment qualified according to written protocols? Is the qualification documented? Yes X No ☐
- Are there written procedures describing the proper operation for all equipment? Yes X No ☐
- Is equipment maintained and calibrated according to a preventive maintenance schedule? Yes X No ☐
- Are the calibration maintenance intervals based on the manufacturers' specified frequencies? Yes X No ☐
- Are records maintained for the use, maintenance and calibration operations? Yes X No ☐
- Are there written procedures for cleaning, specifying cleaning agents and methods? Yes X No ☐
- What are the active ingredients in the cleaning agents?

- Are there approved cleaning agents? Yes ☐ N/A X

- Are the lubricants for our equipment specified for food and pharmaceutical use? Yes [ ] No [X]
- Are any of the cleaning operators performed by contractors? Yes [ ] No [X]
- Are there data to show that the residues left by the cleaning and/or sanitizing agent are within acceptable limits when cleaning is performed in accordance with the approved method? Yes [ ] N/A [X]
- Is there an adequate system to assure that unclean instruments and utensils are not used? Yes [ ] No, testing items are kept clean [X]
- Is there proper storage of cleaned instruments so as to prevent contamination? Yes [X] No [ ]
- Is there an adequate system, described in a SOP, for controlling changes to methods, documents, and equipment, and requiring evaluation of need for re-qualification or re-validation? Yes [X] No [ ]

7.0 PRODUCTION/TRACEABILITY/OPERATIONS

CONTROL OF SUPPLIES

- Can you trace a shipment of your product back to a specific batch or lot number? Yes [X] No [ ]
- Do you have a procedure for segregating incoming raw materials until you have determined that they are acceptable? Yes [ ] No [X]
- Is there a system in-place to ensure that materials are only purchased from Approved Suppliers? Yes [X] No [ ]
- Are batch records used to document the material, equipment and processes used in production? Yes [ ] No [X]
- Is there a procedure for confirming vendor test results? Yes [X] No [ ]
- Are written procedures for the receipt, testing and release for use of all materials followed? Yes [X] No [ ]
- Are there written specifications for each type of material used for production activities? Yes [X] No [ ]

PRODUCTION

- Is traceability of materials used maintained throughout the entire manufacturing process? Yes [X] No [ ]
- Is there a Process Monitoring system? Yes [X] No [ ]
- Is the system Validated? Yes [ ] No [X]
- Is manufacturing monitored at planned, critical, intervals? Yes [X] No [ ]
- Is there a procedure for the documentation and investigation of non-conformances? Yes [X] No [ ]
- Do you have a recall procedure/policy? Yes [X] No [ ]
- Are adverse trends addressed, and is appropriate management notified? Yes [X] No [ ]

7.0 QUALITY PROGRAM

DOCUMENT CONTROL

- Are there written SOPs for all areas of the operation? Yes X No
- Are SOPs periodically reviewed and updated as necessary? Yes X No
- Is a history of SOP revisions maintained? Yes X No
- Is there a SOP for document control (such as Batch Records and test results)? Yes X No
- How do you maintain customer-supplied specification files?

electronically

TEST FAILURES / OUT OF SPECIFICATION RESULTS

- Is there a SOP for investigation of out-of-specification (OOS) test results to assure that a uniform procedure is followed to determine why the OOS result occurred and that corrective actions are implemented? Yes X No
- Are non-conformances tracked? Yes X No
- Are non-conformance trended? Yes X No

QUALITY AUDIT PROGRAM

- Is there an internal quality audit program that reviews all areas of the operation to verify that SOP and other procedures and policies are being followed, and to determine effectiveness of the quality systems? Yes X No

COMPLAINT HANDLING

- Is there a program, described in a SOP, for handling complaints, complaint investigations, and implementing corrective actions where indicated? Yes X No
- Are reports of complaints and investigations provided to appropriate parties, including management? Yes X No

CHANGE CONTROL

- Do you have a Process Control Program? Yes X No
- Do you notify your customers in advance of major changes to processes/materials?

  Yes No X Trials are conducted and reviewed

  IF YES, how far in advance are your customers notified?

7.1 DECLARATION OF ORIGIN

• Is the material manufactured from a synthetic process?	Yes	No X
• Is the material issued of a fermentation or cell culture process?	Yes	No X
• Are materials of vegetable origin involved?	Yes	No X
• Are materials of human or animal origin involved?	Yes	No X
• Has the material, or any components been treated with sewage sludge?	Yes	No X
• Is product produced or has been exposed to radiation?	Yes	No X

- Declaration of Origin: These products are manufactured from high purity, mined gypsum rock from Michigan. Processing is limited to fine grinding, air classification and / or high temperature exposure. The Detroit, MI plant, which only manufactures gypsum based products, has been registered in accordance with the Bioterrorism Act of 2002 and the Food Safety Modernization Act of 2011. The plant adheres to Good Manufacturing Practices (GMP).

MISC PRODUCT INFORMATION

GENETICALLY MODIFIED ORGANISMS (GMO)

USG Feed Grade Products are not derived from or formulated with any genetically modified organisms (GMO).

KOSHER/HALAL STATUS

• Is the product certified as "Kosher"? X Yes No
(Certified through Chicago Rabbinical Counsel)

• Is the product certified as "Halal"? Yes X No

(Certified through "The Islamic Food and Nutrition Counsel of America")

GRAS INFORMATION

All USG Feed Grade Products are manufactured from high purity, naturally occurring calcium sulfate dihydrate (gypsum). Calcium Sulfate is affirmed as Generally Recognized As Safe (GRAS) per the FDA Administration under Title 21, Volume 3, Part 184.

BSE-TSE INFORMATION

All USG Feed Grade Products are free from (BSE) Bovine Spongiform Encephalopathy and (TSE) Transmissible Spongiform Encepalopathy.

ROHS AND CONEG COMPLIANCE

No additives or other ingredients, including polybrominated flame retardants (PBB and PBDE), melamines or bisphenol A are used in the manufacturing of these products. The cadmium level is well below 100 ppm and is not detected when analysis is conducted at a 0.1 ppm detection level. The total sum of lead, mercury and hexavalent chromium is less than 10 ppm. Therefore, the above listed products meet RoHS and CONEG compliance criteria.

ALLERGEN INFORMATION

All USG Feed Grade Products made at our plant in Detroit, MI are provided from high purity naturally occurring mined calcium sulfate, Dihydrate (gypsum). The processing of these materials is limited to fine grinding and/or high temperature exposure. They have not been irradiated and are produced in facilities that are solely dedicated to the production of gypsum-based products. They do not contain, or come in contact with any additives, processing aids, preservatives, or allergens: including, but not limited to:

- Alcohol
- Animal Origin Products
- Autolyzed Yeast/ Yeast Extracts
- Barley Products
- Beef or Beef Derivatives
- BHA
- BHT
- BSE/TSE
- Butyl Paraben
- Celery
- Chocolate/Chocolate Derivatives
- Cis or Trans Fatty Acids
- Corn Products
- Dairy Derivatives
- Dairy Products
- Egg Products
- Estragole
- FD&C Colors
- Fish/Shell Fish Products
- Genetically Modified Organisms (GMO)
- Gluten
- Hydrolyzed Animal Protein
- Hydrolyzed Plant Protein
- 3-MCPD (MPC/DCP)
- Monosodium Glutamate
- Mustard
- Nut or Nut Derivatives
- Oat Products
- Peanuts Products
- Pork or Pork Derivatives
- Rye Products
- Safflower Products
- Sesame
- Soy Products
- Sulfites
- Sunflower Products
- TBHQ
- Tocopherols
- Wheat Products

MISC PRODUCT INFORMATION

CONTAMINANTS

• Does your material contain natural latex or derivatives of natural latex?	Yes	No X
• Do you add Melamine to any of your products?	Yes	No X
• Does your material contain preservatives or antioxidants?	Yes	No X
• Can your material be potentially contaminated with dioxins?	Yes	No X
• Does your material contain Aflatoxins, Fungi or Mycoplasma?	Yes	No X
• Does your product contain steroids?	Yes	No X
• Does product contain or is it warehoused with medicated feed additives?	Yes	No X
• Does your product contain mammalian protein?	Yes	No X

SHELF LIFE INFORMATION

USG Calcium Sulfate Feed Grade should be kept unopened in a dry, stable environment indoors and should be used within one year of the manufacturing date that is located on the bag.

For Product Information and Literature:
800-USG-4YOU (874-4968) or visit usg.com

Manufactured by
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