USG
Gypsum
Solutions

2025 **USG Food and Pharmaceutical** Survey Guide

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CONTENTS

USG FOOD AND PHARMACEUTICAL PRODUCTS

1. USG Snow White® F&P

The following documents can be found on usg.com:

- Product Specification Sheet
- SDS Sheet
- AIB Audit Certificate
- Kosher Certificate
- Halal Certificate
- ISO certificate

PLANT ADDRESS INFORMATION:

Site Name: United States Gypsum Company

Address: 300 Hwy 51-A, Southard OK, 73770

Phone: 580-822-6100 FAX: 580-822-6125

KEY CONTACTS:

Quality Forman: Marsha Mackie

Phone: 580-822-6211 Email: mmackie@usg.com

Production Manager: Alan Parker

Phone: 580-822-6105 Email: alparker@usg.com

Plant Manager: Matt Bright

Phone: 580-822-6132 Email: mbright@usg.com

Customer Service Center:

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

1.0 GENERAL INFORMATION

- Is your company: Private: X Public: Union: Union Name:
- Number of years in business: 123 years
- How many shifts are in operation? 2
- Is your facility registered under the FDA Bioterrorism Registration program? Yes X No
- If so what is the FDA Bioterrorism Registration Number? 13012715174
- Can you provide a Certificate of Analysis on every lot of product supplied? Yes X No

2.0 FOOD SAFETY

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

  IF YES, provide name of contracting service: Orkin
- 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 a designated manufacturing system
- Do you conduct a 3rd party audit of your food safety systems? Yes X No

  IF YES, name of 3rd party auditors: FSSC

  Date of last audit: (month/day/year) May 2024
- Are there provisions for power backup sources for critical systems if main power should fail? Yes X No
- 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		Erie Magnetics above packer, model 8x24 Deep Reach Magnet
Screens/sieve?	X		3/8 inch Sweco Screen
Filters?		X	
Metal Detector?	X		Eriez, model EX-DSP 10x26 HI

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? ISO 9001 : 2015

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: (month/year) July 2024

- 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: DQS Inc.

Date of last audit: (month/day/year) 5/9/24

- 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 [ ]
- Do you use a third-party laboratory for testing? Yes [X] No [ ]
- What monographs does the material(s) comply with?

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

Other [X] (Detail)

NF- National Formulary

- What testing functions does your laboratory have?

HPLC [ ] GC [ ] FTI [ ] AAS [ ] ICP [X] UV [ ] TOC [ ] NMR [ ] NIR [ ]

Other [ ] (Detail)

- How many staff in your laboratory? 3
- Are your methods validated? Yes X No
- Are there written specifications for raw materials and finished products? 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? **F&P retains are kept for 5 yrs**
- Is your facility compliant with Q3C Impurities: Residual Solvent testing for the subject product?

  Yes No N/A X because **No solvents are 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
- Was environmental testing conducted? 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 methods? Yes X No
- Are there approved cleaning agents? Yes N/A X
- What are the active ingredients in the cleaning agents?

  Dry cleaning only, (ie. no chemicals) no liquids or solvents are used.

• Are the lubricants for our equipment specified for food and pharmaceutical use?	Yes X	No
• 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 laboratory instruments and utensils are not used?	Yes X	No
• 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 X	No
• 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 X	No
• 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 X	No
• 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

8.0 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?

Plant level by the way of operating bulletin and also with Sales Reps.

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 No X

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 X No Trials are conducted and reviewed

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

Prior to next shipment

8.1 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
- Is sulfuric acid used in the process or extraction? Yes No X
- Declaration of Origin: These products are manufactured from high purity, mined gypsum rock from Oklahoma. Processing is limited to fine grinding, air classification and / or high temperature exposure. The Southard, OK 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. This plant adheres to Good Manufacturing Practices, (GMP), is ISO 9001:2015 certified and follows a Hazard Analysis Critical Control Point (HACCP) program.

ANALYTICAL TESTING

SNOW WHITE® FILLER F&P

• Do you do an Aerobic Plate Count, APC?	Yes X	No
• Do you test for Coliforms?	Yes X	No
• Do you test for Escherichia coli?	Yes X	No
• Do you test for Salmonella spp.?	Yes X	No
• Do you test for Staphylococcus aureus?	Yes X	No

MISC PRODUCT INFORMATION

GENETICALLY MODIFIED ORGANISMS (GMO)

USG F&P 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 Council)

• Is the product certified as "Halal"? X Yes No
(Certified through "The Islamic Food and Nutrition Counsel of America")

CALIFORNIA PROP 65 INFORMATION

USG F&P products **"DO NOT CONTAIN"** any chemicals found on the current California Proposition 65 List of Chemicals.

GRAS INFORMATION

All USG F&P 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, Chapter 1, Part 184.

BSE-TSE INFORMATION

All USG F&P 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.

NON-ORGANIC PRODUCT COMPLIANCE

Products are manufactured from naturally occurring rock in the ground. They are approved for use under the USDA National Organic Program (section 205.605) as "nonagricultural substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

ALLERGEN INFORMATION

All USG F&P products made at our plant in Southard, OK 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,solvents, 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
- Butyl Paraben
- Celery
- Chocolate/Chocolate Derivatives
- Cis or Trans Fatty Acids
- Corn Products
- Dairy Products
- Dairy Derivatives
- Egg Products
- Estragole
- FD&C Colors
- Fish/Shell Fish Products
- Gluten
- Hydrolyzed Animal Protein
- Hydrolyzed Plant Protein
- Lupin
- 3-MCPD (MPC/DCP)
- Monosodium Glutamate
- Mustard
- Nut or Nut Derivatives
- Oat Products
- Peanuts Products
- PFAS
- Pork or Pork Derivatives
- Rye Products
- Safflower Products
- Sesame
- Soy Products
- Sulfites
- Sunflower Products
- Tocopherols
- TBHQ
- Wheat Products

NO ANIMAL TESTING STATEMENT

Products have not been the subject of animal testing by or on behalf of USG.

SEWAGE STATEMENT

No sewage sludge or sewage treatment facilities are in proximity to the manufacturing plant.

MISC PRODUCT INFORMATION

All USG F&P Products are guaranteed to meet the specifications of the Food Chemicals Codex and the National Formulary listed below:

	Food Chemicals Codex	National Formulary
Arsenic	3.0 ppm max.	3.0 ppm max.
Selenium	30.0 ppm max.	30.0 ppm max.
Fluorine	30.0 ppm max.	30.0 ppm max.
Heavy Metals	—	10.0 ppm max.
Iron	—	100.0 ppm max.
Lead	2.0 ppm max.	—
Calcium Assay	98.0% min.	98.0% min.

Note–The materials listed above are tested weekly and reported on each shipment's Certificate of Analysis.

NUTRITIONAL INFORMATION FOR FOOD & PHARMACEUTICAL PRODUCTS

Nutrition information is based on amount per 100 grams.

	Snow White® Filler Anhydrous Calcium Sulfate
Total Calories	0.0
Calories from Fat	0.0
Total fat (g)	0.0
Saturated Fat (g)	0.0
Cholesterol (mg)	0.0
Sodium (mg)	0.0
Potassium (mg)	0.0
Total Carbohydrate (g)	0.0
Dietary Fiber (g)	0.0
Sugars (%)	0.0
Protein (% U.S. RDA)	0.0
Vitamin A (% U.S. RDA)	0.0
Vitamin C (% U.S. RDA)	0.0
Vitamin D (mcg)	0.0
Iron (mg)	0.0
Calcium (mg)	29,200
Moisture (g)	0.33
Ash (g)	99.7

MISC PRODUCT INFORMATION

ELEMENTAL IMPURITIES INFORMATION

Element	Potentially present	Southard, OK Calcium Sulfate ug/g	Oral Daily Dose PDE limits ug/day	max. daily intake 1000 mg FG ug
Cadmium	Y	< 0.5	25	0.5
Lead	Y	2.2	5	2.2
Arsenic	Y	< 1	1.5	1
Mercury	Y	< 0.005	15	0.005
	Expected to be present			
Iridium	ND		100	
Osmium	ND		100	
Palladium	ND		100	
Platinum	ND		100	
Rhodium	ND		100	
Ruthenium	ND		100	
Chromium	Y	0.5		
Molybdenum	Y	1.6	100	1.6
Nickel	Y	1.3	500	1.3
Vanadium	Y	1.2	100	1.2
Copper	Y	1	1000	1
Manganese	Y	11.4		

Note–ND=Non-Detected

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

PACKAGING GUARANTEE

Applicable to SNOW WHITE® Filler Food and Pharmaceutical Products

This is to certify that the composition and ingredients used in the adhesives and papers are within the limits required for use in contact with food as stipulated by:

US FDA: Paper under FAR 21 CFR 176.170 and 21 CFR 176.180 Adhesives under FAR 21 CFR 175.105
Canada: Status of “No Objection” by health Protection Branch, Health and Welfare Canada

This certificate is based on approval from our supplier. Use of these packages is subject to good manufacturing practices and any limitations which are part of the regulations.

CONTINUING GUARANTEE

Applicable to SNOW WHITE® Filler Food and Pharmaceutical Products (hereafter, "article" or "articles")

The article or articles composing each shipment or other delivery made by United States Gypsum to, or on the order of: is/are hereby guaranteed by the undersigned seller, as of the date of such shipment or delivery to our customer, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, as amended, or any similar state of municipal law; and not an article which may not, under the provisions of Section 404 or 505 of such Act, be introduced into interstate commerce, or, in the case of similar state of municipal laws, intrastate commerce. This guarantee supersedes any and all prior food and drug guarantees. This is a general and continuing guarantee and shall remain in full force and effect until written receipt by or of written notice of its revocation by the seller or until December 31, 2024.

SHELF LIFE INFORMATION

Snow White® F&P should be kept unopened in a dry, stable environment indoors. Snow White F&P should be used within 12 months 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
United States Gypsum Company
550 West Adams Street
Chicago, IL 60661
A Subsidiary of USG Corporation

IG1888/rev. 1-25

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