2.1 The Food Safety Team

Arcosa Specialty Materials
BESSIE MILL
FOOD SAFETY PLAN

Food Grade Gypsum

Team Leader

Randy Wenninger – Plant Manager
AIB HACCP Training – 1/2016

Team Members:
Jacob Desouza – Quality Manager – Internal Training – _02/03/2022___
Cole Sisco – Industrial Products Sales- Internal Training – _02/07/2022___
Lisa Kosler- Documentation Specialist – 3rd Party HACCP Training – 10/13/2023
PCQI – 3rd Party Training – 05/06/2021
Mike Spencer- Mill Operator- Internal Training – ____/____/____
Robert Houchin – Mill Operator – Internal Training - _____
Stoney Hartronft – Production Supervisor – Internal Training – ____/____/____
Darcie Rhoads – Lab Tech – Internal Training – ____/____/____
Todd Sneed-Alternate Lab Tech – Internal Training - ____/____/____

- All HACCP team members have successfully completed HACCP training and understand the 7 principles of HACCP.

Food Safety Plan
Ground Calcium Sulfate
(Food & Feed Grade)
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Food Grade Gypsum

Re-assessment History

Reassessment of the HACCP plan: Every establishment shall reassess the adequacy of the HACCP plan **at least annually** and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.

Date	Signature	Event/ Reason
12/20/2013	Signature on file	Revision 1
1/1/2014	Signature on file	Review/verify HACCP Flow Chart Revision 2
1/9/2014	Signature on file	Update Risk Assessment for HACCP plans Revision 3
1/24/2014	Signature on file	Flow, Summary, HACCP Annual Review
2/10/2014	Signature on file	BRC Audit – show Food Grade and Valu Fil Tanks on Flow diagram; update Hazard Analysis to include Tanks on flow diagram. Revision 4
6/3/2014	Signature on file	Updated Monographs; USP 37 –NF 32 & FCC 9th Ed Revision 5
1/9/2014	Signature on file	HACCP Review Management Meeting Verified HACCP Plan Flow Chart
12/17/2015	Signature on file	Vulnerability Assessment complete – HACCP Review Management Meeting – Verify Flow Chart
1/15/2016	Signature on file	Updated HACCP Training for Bobby Richardson and Randy Wenninger
1/11/2017	Signature on file	Annual HACCP Plan Review
1/9/2018	Signature on file	Annual Haccp – management review
1/7/2019	Signature on file	Annual HACCP Plan Review 1-7-19 HACCP plan review, management review meeting.
11/12/2019	Signature on file	HACCP Plan Re-assessment – following voluntary recall.
12/30/2019	Signature on file	Annual reassessment – including customer disclosure program.
1/20/20	Signature on file	Reassess – add specific hazards to biological and pest.
5/6/2020	Signature on file	Update Flow Chart – added magnets at Super Sacks. Updated HACCP training date for L. Kosler.
12/18/2020	Signature on file	Annual Assessment – update HACCP team training
1/6/2022	Signature on file	Annual Assessment – update plant flow chart – changed screen size at prater screen to 50 mesh.

2/7/2022	Signature on file	HACCP – verify plant flow chart/ updated chart to depict magnets at super sack station – 1 magnet for Valu Fil and 2 magnets used for Terra Alba Add Food Grade Lubricant to hazard analysis Internal Haccp training updated Add Receiving of bags to hazard analysis
12/7/2022	Signature on File	Annual HACCP Review – re-evaluate hazard analysis
12/13/2023		Annual HACCP-Review – re-evaluate hazard analysis. Flow chart walk thru.(10/13/2023)

Scope & Summary

No Critical Control Points Identified at This Time

The Hazard Analysis considers food safety through the analysis and control by prerequisite programs of biological, chemical, and physical hazards in the Bessie Grinding Facility. At this time, the hazard analysis did not define any steps to be Critical Control Points based on the following reasoning:

1. Gypsum is a naturally occurring mineral that is mined and ground at the grinding facility. There is a low risk for biological hazards in the raw material. The raw material, ground rock does not support microbial growth. It has no nutritional value and has extremely low water activity. The finished product is a dry finely ground powder.
    a. Biological contamination concerns are being addressed due to product recalls for ground calcium sulfate.
        1. Preventive controls are in place to mitigate occurrences of microbiological hazards.
            a. Contracted trucks dedicated to hauling gypsum rock are used to move raw material from the mine to the grinding facility.
            b. Truck inspections at mine and incoming rock inspections at Bessie plant.
            c. Rock shed – covered, dry, pest free and inspected visually daily prior to production.
            d. Loader cleaned daily prior to production and inspected prior to loading rock into production.
        2. Customer Disclosure Program
            a. Disclosure statement provided to customer according to FSMA requirement for Preventative Controls for Human Food 21CFR117.136 and 117.335 and/or Animal Food 21CFR507.36 and 507.215
                i. Certificate of Analysis (COA) accompanies product includes the disclosure statement.
                ii. Disclosure statement is printed on bagged material. (25 lb., 25 kg. 50 lb. bags)
                iii. Product Data Sheet (PDS) includes the disclosure statement.
            b. Annual written assurance from customer; that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard. 21CFR117.136(a)(2)(ii) and (4) and 21CFR507.36 (a)(2)(ii)(4). (FDA is not requiring customer assurances currently.)

2. No chemical hazards exist in the processing of the ground gypsum.
    a. Pure grade gypsum – meets CFR 184.1230; FCC 12th ED. Pg. 220
    b. Product tests are conducted to verify the "pure grade"
3. Physical hazards are controlled within the processing/grinding of the rock.
    a. The mining process may allow metal exposure from mining equipment to be in the raw material/rock. Controls are in place at the grinding facility to reduce any metal contamination. (See Metal Contamination Risk Assessment)
    b. PROCESSING:
        i. Metal from mining is reduced after passing under the belt magnet after the feed hopper. This magnet will catch more than 99% of all metal from the mine primarily to protect the mill and feed system from potentially damaging metal contamination.
        ii. Any metal greater than 0.25" will cause excessive vibration and noise in the mill resulting in a mill shutdown and inspection.
        iii. The milling and screening process reduce all product to less than 100 mesh or 0.15mm.
        iv. Magnets and screens are in place after milling and before packaging to catch residual tailings. See Metal Contamination Risk Assessment
        v. FDA Hard and Sharp Guidance document recognizes a food safety hazard between 7 mm and 25 mm in size. This could be a choking hazard.

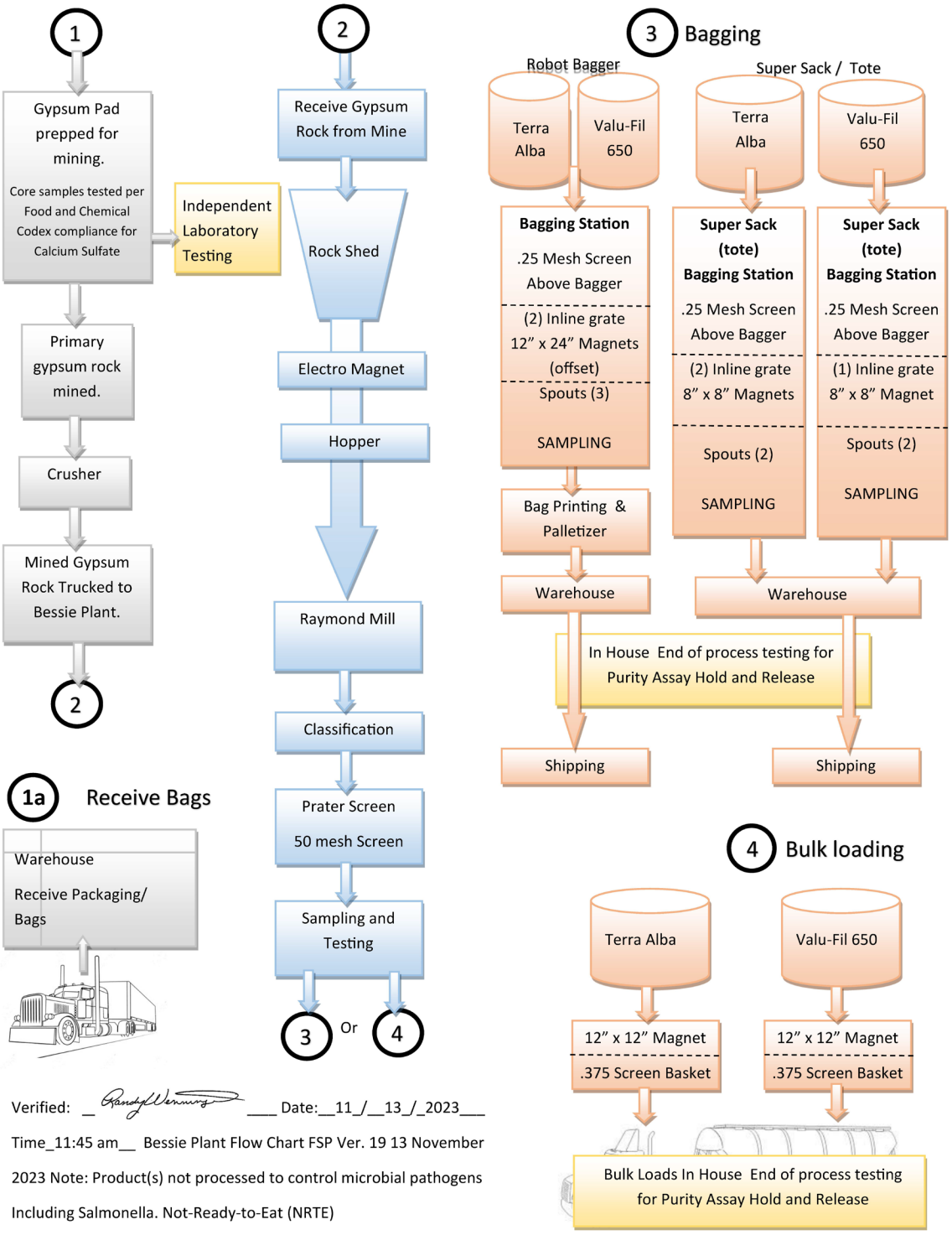
4. Allergens and cross-contamination are non-existent in this production facility. There is one raw material, and the finished product is that raw material ground into a fine powder. No other ingredients are added, and no other products are produced in the Bessie grinding facility. No water or additives are incorporated into the final product.

5. Prerequisite programs are in place at the Bessie Grinding Facility to meet Good Manufacturing Processing Standards and customer requirements.

    a. Supplier Approval Program ensures that food grade packaging is following food regulations and certificates, or letters of conformance required from supplier.

6. Food and/or Feed grade ground calcium sulfate is a Not Ready to Eat (NRTE) additive that requires further processing.

Arcosa Specialty Materials 1113 Main Street, Bessie, OK 73622



Verified: _Randy Wenning_ Date:__11_/__13_/_2023___

Time_11:45 am__ Bessie Plant Flow Chart FSP Ver. 19 13 November 2023 Note: Product(s) not processed to control microbial pathogens Including Salmonella. Not-Ready-to-Eat (NRTE)

INGREDIENT & ORIGIN

Only 1 ingredient is used in Food Grade Ground Gypsum and or Feed Grade Ground Gypsum:

Ingredient(s): Rock - Calcium Sulfate mined in Oklahoma

PRODUCT DESCRIPTION:

Food Grade Gypsum from Calcium Sulfate mined in Oklahoma (origin)
Feed Grade Gypsum from Calcium Sulfate mined in Oklahoma (origin)

FOOD SAFETY CHARACTERISTICS:

Pure grade gypsum – meets 21CFR184.1230 food grade ground gypsum and 21CFR582.5230 feed grade ground gypsum
Low water activity, dry powder, no nutrients

INTENDED USE OF PRODUCT
Food Grade

1. Commercial Baking Industry – since most grains contain less than 0.05% calcium, the fillers are economical sources of supplemental calcium in enriched flour, cereals, baking powder, yeast, bread conditioners and cake icing, the gypsum products can also be found in canned vegetables and artificially sweetened jellies and preserves.
2. Brewing Industry- in brewing industry, calcium sulfate promotes a smoother tasting beer with improved stability and a longer shelf life.
3. Soy beaning Industry – calcium sulfate has been used in China for over 2,000 years to coagulate soy milk to make tofu. Tofu made from calcium sulfate will be softer and smoother with a mild, bland flavor profile.

The FDA permits the use and Limits for GMP of calcium sulfate for food additive are list below

Product Category	Limits (%)
baked goods	1.3 max
confections and frosting	3.0 max
frozen dairy deserts and mixes	0.50 max
gelatins and puddings	0.40 max
rain products and pastas	0.50 max
processed vegetables	0.35 max
all other food categories	0.07 max

Feed Grade

1. Feed grade calcium sulfate contributes to the formation of teeth, proper bone, eggshell, milk, and sulfur-containing amino acids.
2. Feed grade calcium sulfate helps to supply the calcium and sulfur requirements for many types of livestock including dairy cows and laying hens.

SHELF LIFE:

Dry –at ambient temperatures: 1-year shelf life is added to the food grade product

TYPE OF PACKAGE?

Super Sacks (totes), paper sacks

WHERE WILL IT BE SOLD?

Food Processing Industry – further processing as a minor ingredient
Baking, tofu, brewing.
Feed Processing Industry – further processing as a minor ingredient in feed.

LABELING INSTRUCTIONS:

Lot # and production date
All bagged material will have the following disclosure statement printed on the bag.
"This product is not processed to control microbial pathogens."

DISTRIBUTION METHOD

Distributors must disclose the customer disclosure statement to all purchasers.

Direct purchasers are required to sign the customer disclosure agreement prior to purchasing material from the Bessie Grinding facility.

PRODUCTS/INGREDIENTS USED TO PRODUCE PRODUCT:

PRODUCT: Food Grade Ground Gypsum
Feed Grade Ground Gypsum

MEAT/POULTRY AND BYPRODUCTS	INGREDIENTS	BINDERS/ EXTENDERS
N/A	Rock Calcium Sulfate	N/A
SPICES/FLAVORINGS	**RESTRICTED INGREDIENTS**	**PRESERVATIVES/ ACIDIFIERS**
N/A	N/A	N/A
OTHER	**PACKAGING MATERIALS**	**ALLERGENS**
	Kraft – poly lined bags Super Sacks	None

Ingredient	Gypsum Rock
Composition	Mined Gypsum Rock
Origin	USA, Oklahoma
Method of Production	Mined Select grade Gypsum Rock
Packaging and Delivery	Delivered via material handler trucks from mine.
Storage	Dry, covered rock shed.
Preparation and handling	Manually loaded onto mill conveyor
Acceptance Criteria	Clean and Dry

Ingredient Hazard Analysis

Hazard Type	Potential Hazard Description	Likelihood of Occurrence	Severity of Occurrence
Biological	Microbiological	Slight	Major
Chemical	None		
Physical	Mining Metal	Likely	Major
Radiological	None		
Fraud	None		
Malicious	Nil		
Allergen	Nil		

Reference

HACCP Plan Summary for biological, chemical, physical hazards, and radiological hazards.

INGREDIENT / PACKAGING ASSESSMENT

PACKAGE MATERIAL	**STORAGE REQUIREMENT**	**BIOLOGICAL HAZARD (YES/NO)/WHAT**	**CHEMICAL HAZARD /ALLERGEN (YES/NO)/WHAT**	**PHYSICAL HAZARD (YES/NO)/WHAT**
Kraft Poly Lined Bags	Dry covered storage	None	None	None
Polypropylene Woven Super Sacks	Dry covered storage	None	None	None

Packaging Suppliers provide compliance documentation.

Hazard Analysis

Product: Gypsum - ground calcium sulfate

L = Likelihood: 1 2 3 4 5 (low to high)
C = Consequence: 1 2 3 4 5 (low to high)

Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
1. Receive Gypsum Rock from Mine	**B** –pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. Receiving incoming rock (SOP)		NO
	C –none	1	4	5	No			NO
	P –Metal- metal from mining	4	3	7	No	Possible metal contamination from the supplier Receiving Program, Supplier Program.		NO
1.a. Receiving Bags from supplier	**B - pathogens**	1	2	3	No	Supplier approval program – certificate of compliance from suppliers		NO
	C - none	1	2	3	No	Supplier approval program – certificate of compliance from suppliers		NO
	P - none	1	2	3	No	Supplier approval program – certificate of compliance from suppliers		NO
2.Rock Shed	**B** –pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk Daily Rock Shed Inspection		NO
	C – None	1	2	3	No			NO

Hazard Analysis

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Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
	P - Metal /Other Contamination, insects/rodents	1	3	4	No	Possible metal contamination. Metal pieces from the mining equipment – visual incoming inspection of rock. Pest control program.		NO
3.Rock loaded onto mill conveyor	**B** –pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. Daily Loader Inspection		NO
	C –none							
	P-metal from mining	4	3	7	No	Electro-magnet pulls metals from mining from rock before entering mill.		NO
4. Mill Feed conveyor	B – pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk.		NO
	C- none							
	P – Metal from equipment	2	4	6	No	Possible metal contamination. Metal pieces from the mining equipment.		NO

Hazard Analysis

Product: Gypsum - ground calcium sulfate

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Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
5. Roller Mill	B-pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk (Roller Mill is an enclosed system)		NO
	C-Equipment lubricants	2	5	7	No	Supplier approval programs – use of food grade lubricants with supplier conformance letter		NO
	P – Metal shavings from equipment	2	4	6	No	Metal shavings from milling.		NO
6. Classification	B-pathogens - Salmonella	1	5	8	No	Adherence to prerequisite cleaning program to minimize risk (enclosed)		NO
	C-None							
	P -Metal shavings from milling	2	4	6	No	Magnet and screen in place at prater.		NO
7. Ground Gypsum blown to tanks	B-Pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk (enclosed)		NO
	C-None							

Hazard Analysis

Product: Gypsum - ground calcium sulfate

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Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
	P-metal shavings from milling					Metal shavings from milling		
8. Bulk Loading	B-Pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk.		NO
	C-None							
	P-metal shavings from milling					Metal shavings from milling – Magnet, .375 Screen basket (prevents objects from falling into pneumatic trailer)		NO
9. Blown to Bagging	B-pathogens- Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. (enclosed)		NO
	C-None							
	P-None							
10. Bagging Stations (Super Sack	B-pathogens- Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk GMP's. Cleaning and housekeeping, daily pre-checks.		NO

Hazard Analysis

Product: Gypsum - ground calcium sulfate

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C = Consequence: 1 2 3 4 5 (low to high)

Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
and/or Kraft Bags)	C-None							
	P-None					Metal shavings from milling – Magnets located above bagging spouts and Screens located above bagging spouts. Supplier approval program – bag suppliers.		NO
11. Palletizer & bag printing (for kraft paper bags only)	**B-**pathogens - Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. Proper package storage. Cleaning and housekeeping – daily warehouse pre-checks.		NO
	C-none					Food Grade ink used in printer. Supplier Approval Program		NO
	P-None							

Hazard Analysis

Product: Gypsum - ground calcium sulfate

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Process Step	Potential hazard Introduced, controlled, or enhanced at this step B=Biological C=Chemical P=Physical	Likelihood	Consequence	Risk = L+C	Is the potential food safety hazard reasonably likely to occur? Yes R ≥ 9 No R ≤ 8	Justification for decision made in previous column and/or Pre-requisite program(s) used to reduce risk	(Yes, from column 6) What control measures can be applied to prevent, eliminate, or reduce the hazards being addressed in the HACCP plan or "Subsequent Step Controls Hazard"	CCP # or No
12. Warehouse	**B-**pathogen- Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. Storage, Dispatch, Housekeeping, and cleaning procedures.		NO
	C-none							
	P-Pest- insect/rodent	1	4	5	No	GMP's - Master Cleaning, Daily Cleaning, Pest Control Program, Storage Procedures		NO
13. Shipping	**B-**pathogens- Salmonella	1	5	6	No	Adherence to prerequisite cleaning program to minimize risk. Dispatch and Storage procedures.	Customer Disclosure and Written Assurance required from purchasers	NO
	C-none							
	P- debris in shipping trailer	1	4	5	No	GMP's - Truck Inspection Program, Shipping Procedures		NO

There are NO Critical control points.

- Product(s) are not shipped to customers without signed Written Disclosure and Written Assurance per FDA regulations; 21 CFR 117.136 and 117.335 and 507.36 and 507.215.
- All product is shipped with documentation disclosing: Product not processed to control pathogens, including Salmonella.
- All product COA's have written disclosure: Product not processed to control pathogens, including Salmonella.

Calcium Sulfate

Published in: FCC 11 2S | FCC 11 3S | FCC 12
First Published: Prior to FCC 6

$CaSO_4$
Formula wt, anhydrous 136.14
$CaSO_4 \cdot 2H_2O$
Formula wt, dihydrate 172.18
INS: 516
CAS: anhydrous [7778-18-9]
CAS: dihydrate [10101-41-4]

DESCRIPTION

Calcium Sulfate occurs as a fine, white to slightly yellow-white powder. It is anhydrous or contains two molecules of water of hydration.

FUNCTION: Nutrient; yeast food; dough conditioner; firming agent; sequestrant

PACKAGING AND STORAGE: Store in well-closed containers.

IDENTIFICATION

- **A. PROCEDURE**

  Sample solution: Dissolve 200 mg of sample by warming it with a mixture of 4 mL of 2.7 N hydrochloric acid and 16 mL of water.

  Analysis: Add 5 mL of *ammonium oxalate TS* to 10 mL of the *Sample solution.* Retain the remainder of the solution for Identification

  Procedure B below.

  Acceptance criteria: A white precipitate forms.

- **B. PROCEDURE**

  Analysis: Add *barium chloride TS* to the retained 10 mL of *Sample solution* prepared for *Procedure A* above.

  Acceptance criteria: A white precipitate forms that is insoluble in hydrochloric and nitric acids.

ASSAY

- **PROCEDURE**

Sample solution: Disperse 250 mg of sample in 100 mL of water and 4 mL of 2.7 N hydrochloric acid. Boil to dissolve the sample and cool the solution.

Analysis: While stirring the *Sample solution*, preferably with a magnetic stirrer, add about 30 mL of 0.05 M disodium EDTA from a 50-mL buret. Then, add 25 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue indicator. Continue the titration with disodium EDTA to a blue endpoint. Each mL of 0.05 M disodium EDTA is equivalent to 6.807 mg of $CaSO_4$.

Acceptance criteria: NLT 98.0% of $CaSO_4$, calculated on the dried basis

IMPURITIES

INORGANIC IMPURITIEs

- **FLUORIDE, *Fluoride Limit Test, Appendix IIIB***

Sample: 1.67 g

Acceptance criteria: NMT 0.003%

- **LEAD, *Lead Limit Test, APDC Extraction Method, Appendix IIIB***

Acceptance criteria: NMT 2 mg/kg

- **SELENIUM, *Selenium Limit Test, Method II, Appendix IIIB***

Sample: 200 mg

Acceptance criteria: NMT 0.003%

SPECIFIC TESTS

- **Loss ON DRYING, *Appendix IIC*:**

Acceptance criteria Anhydrous: NMT 1.5%

Dihydrate: Between 19.0% and 23.0%

Please check for your question in the FAQ's before contacting USP.

CALCIUM SULFATE Gina Clapper
Senior Scientific Liaison
(301) 692-3626

F12015 Food Ingredients 2015

Page Information

FCC 11 - page 227

- FCC 10 - page 250
- FCC 9 - page 222

FI2015 Food Ingredients 2015

CFR - Code of Federal Regulations Title 21

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2019]
[CITE: 21CFR184.1230]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 184 -- DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1230 Calcium sulfate.

(a) Calcium sulfate ($CaSO_4$, CAS Reg. No. 7778-18-9 or $CaSO_4.2H_2O$, CAS Reg. No. 10101-41-4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by complete dehydration of gypsum, below 300 deg. C, in an electric oven.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 66, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) The ingredient is used as an anticaking agent as defined in 170.3(o)(1) of this chapter, color and coloring adjunct as defined in 170.3(o)(4) of this chapter, dough strengthener as defined in 170.3(o)(6) of this chapter, drying agent as defined in 170.3(o)(7) of this chapter, firming agent as defined in 170.3(o)(10) of this chapter, flour treating agent as defined in 170.3(o)(13) of this chapter, formulation aid as defined in 170.3(o)(14) of this chapter, leavening agent as defined in 170.3(o)(17) of this chapter, nutrient supplement as defined in 170.3(o)(20) of this chapter, pH control agent as defined in 170.3(o)(23) of this chapter, processing aid as defined in 170.3(o)(24) of this chapter, stabilizer and thickener as defined in 170.3(o)(28) of this chapter, synergist as defined in 170.3(o)(31) of this chapter, and texturizer as defined in 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 1.3 percent for baked goods as defined in 170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in 170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in 170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in 170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in 170.3(n)(23) of this chapter, 0.35 percent for

processed vegetables as defined in 170.3(n)(36) of this chapter, and 0.07 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980; 45 FR 26319, Apr. 18, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

Metal Contamination Risk Assessment

Lee Graves, Director of Operations

ARCOSA
SPECIALTY MATERIALS

Summary

The following assessment is intended to determine exposure to metal contamination and to analyze the control measures in place and their ability to effectively identify and mitigate potential contamination hazards. In addition, an analysis of the effectiveness of installing additional metal detection equipment will be explored.

As a general guiding principle to this analysis, it is understood that due to the abrasive nature of grinding and rotating equipment, there will be a certain amount of fine metal particles created and that this presence is both expected and acceptable. Fine metal particles are considered particles smaller than 1.5mm, which is the maximum detectable size of contamination that is typically detectable by metal detection equipment.

Exposure to Metal Contamination

Exposure from Mining Process

Metal Type: Ferrous

Description: Bolts, Milling Teeth, Equipment Cutting Edges, Etc.

Size: Large (2-6 inches)

Potential Non-Ferrous Exposure: Improbable

Control Measures:

1. Belt Magnet: The Belt Magnet after feed hopper will catch more than 99% of all metal from mine. The primary function of this control measure is to protect the mill and feed system from potentially damaging metal contamination. Failure of this process would result in costly Mill damage and down time
2. Mill: The Mill acts as a control measure. Any large (greater than 0.25”) pieces that enter the mill will be noticed by the operator because of the large amount of noise and vibration caused by the contamination. This would result in a mill shutdown and inspection by the operator

Exposure from Milling Process

Metal Type: Ferrous and Brass

Description: Ground ferrous metal particles from grinding mill, brass bushings inside of mill that hold journals in place, worn ferrous metal from airlocks

Size: very fine (below 100 mesh or 0.15mm)

Potential Non-Ferrous Exposure: Extremely unlikely as it would only be able to occur within the Mill and is impossible for the contaminant to pass through both the Classifier

and the Prater Screen. If a large piece of brass were to dislodge, it would be because of a catastrophic failure within the Mill that would result in the journal dislodging from its mount. After which, the mill must be able to grind the large brass particle to a size that would pass the rotating classifier (designed to keep particles above 100 mesh within the mill). It is expected that the mill would be unable to turn with a dislodged journal. If this did happen, the Prater Screener with a 40-mesh screen would also have to fail to allow this to pass into the conveying system.

Control Measures:

1. Mill: The Mill acts as a control measure. Any large (greater than 0.25") pieces that enter the mill will be noticed by the operator because of the large amount of noise and vibration caused by the contamination. This would result in a mill shutdown and inspection by the operator
2. Classifier: The classifier acts as a particle sizing control. This equipment is set so that particles will not pass through if they are larger than approximately 100 mesh (0.15mm). Failure by this equipment is interlocked to cause an automatic mill shutdown
3. Magnet: Located above the Prater Screener and below the Cyclone Airlock, this magnet is intended to catch any ferrous metal before it enters the Screener. This is the first magnet in the system to catch ground metal fragments. Because the classifying process is designed to restrict large particles through, metal found on this magnet will be very fine. This magnet is inspected twice per 24 hours period. We believe that 99% of all ferrous metals leaving the mill are caught in this first magnet.
4. Prater Screener: This equipment is in place to catch any anomalous oversize particles that might make it through the classifier. It has a screen size of 50 mesh (0.3mm). Oversized particles are discharged out of the system
5. Documentation and Inspection: The Mill Operator takes samples each hour and visually inspects the oversize that is coming from the Prater. The samples are tested in an Alpine sieve over both a 325 mesh and 50 mesh screens. The primary function is to ensure the proper grind of the material. Out of spec particles will cause the mill operator to adjust mill settings (for minor aberrations) or to shut down the mill and inspect (in cases where large particles are present. Large particles are particles larger than 50 mesh).

Exposure from Conveying and Storage

Metal Type: Ferrous

Description: Minute risk for fine metal particles that come from rotation and contact within the blower used for pneumatic conveying, extremely fine metal worn from particle abrasion within the pneumatic lines, and fine metal worn from particle abrasion within the storage tanks. Since gypsum is not considered an abrasive mineral the most likely source is from the blower system and not from the particles wearing against blow lines and tank walls.

Potential Non-Ferrous Exposure: None

Control Measures:

1. Dual Magnet: For product that leaves the plant in bulk trucks. These magnets catch any remaining ferrous metals that may be generated in the post-milling process within the plant. Because confinement of non-ferrous metals has already occurred and there is zero exposure after this confinement, magnets will suffice for protection from contamination reaching the customer. The magnet is checked after each bulk truck has finished loading. Any metal present will be inspected for size to determine if it is acceptable exposure
2. Bagging Process: Material sent to the bagging process will pass through bagging control process

Exposure from Bagging Process

Metal Type: Ferrous

Description: Slight exposure to contamination from rotating airlocks. This metal will be very fine as it is purely abrasion related and does not meet any shear stress. Catastrophic failure is extremely unlikely.

Size: Very fine particles

Potential Non-Ferrous Exposure: None

Control Measures:

1. Magnet: A magnet is located above the bagger that catches metal contamination before it can enter the bags. This magnet is visually inspected twice per bagging shift. If contamination is identified, food grade products that are bagged during the time since the last inspection are quarantined and handled as non-conforming product. Magnet inspections are documented by the operator and checked by the supervisor.

Effectiveness of Proposed Metal Detection Equipment

The metal detection equipment is designed to measure conductivity of particles. The conductivity is proportional to the size of the particle. The metal detection equipment, therefore, can identify metal contamination of particles of a certain minimum size. For ferrous metals, the smallest size that can be typically measured is 1.5mm. For non-ferrous metals, this minimum identifiable size is larger, due to the smaller degree of conductivity of non-ferrous metals. This minimum detectable size is also limited by the size of the detecting aperture. A larger aperture has less sensitivity.

Due to the fact that the gypsum grinding process is a closed system and because of internal size restriction methods inherent in the grinding process, and the fact that the largest particle size allowed through our system is an order of magnitude smaller than the lowest detectable limit of

the detecting unit, it is unlikely if not impossible for a metal particle to either be introduced or generated that will be of a size that an installed metal detector would identify any contamination or act as any meaningful control measure.

Conclusion

While it is true that metal contamination exposure exists within the plant, the process control measures that exist within the plant mitigate potential metal contamination exposure from reaching the customer. Additionally, the installation of metal detection equipment will have no practical benefit in decreasing any remaining exposure.

Recommendations

While the existing equipment is sufficient to protect customers from contamination of metal within the delivered product, a review of inspection and documentation procedures will occur and be updated. Adjustments will increase confidence that these procedures are followed by plant employees.

Reference

CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects

BACKGROUND: Hard or sharp foreign objects in food may cause traumatic injury including laceration and perforation of tissues of the mouth, tongue, throat, stomach, and intestine as well as damage to the teeth and gums. From 1972 through 1997, the FDA Health Hazard Evaluation Board evaluated approximately 190 cases of hard or sharp foreign objects in food. These include cases of both injury and non-injury reported to FDA. The Board found that foreign objects that are less than 7 mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly. The scientific and clinical literature supports this conclusion. Hard or sharp natural components of a food (e.g., bones in seafood, shell in nut products) are unlikely to cause injury because of awareness on the part of the consumer that the component is a natural and intrinsic component of a particular product. The exception occurs when the food="s" label represents that the hard or sharp component has been removed from the food, e.g., pitted olives. The presence of the naturally occurring hard or sharp object in those situations (e.g., pit fragments in pitted olives) is unexpected and may cause injury. FDA has established Defect Action Levels for many of these types of unavoidable defects in other Compliance Policy Guides and therefore they are not subject to the guidance in this document. REGULATORY ACTION GUIDANCE: The following represent the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and direct reference import detention to the appropriate Field Offices within the Human and Animal Food Program*. a**. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length**. and b. The product is ready-to-eat, or according to instructions or other guidance or requirements, it requires only minimal preparation steps, e.g., heating, that would not eliminate, invalidate, or neutralize the hazard prior to consumption. Samples found to contain foreign objects that meet criteria a. and b., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1). The following represent the criteria for recommending legal action to CFSAN Office of *Compliance, Division of Enforcement* (HFS-605). c. The product contains a hard or sharp

foreign object that measures 7 mm to 25 mm in length, and the product requires additional preparation or processing that may have an effect on the presence of the foreign objects in the finished food. For example, additional sifting of a product may or may not remove foreign objects, depending on the measurements of the objects and the mesh aperture of the sifter. In these situations, the preparation or processing of the food must be described in the recommendation submitted by the appropriate *office within the Human and Animal Food Program*. or d. The product contains a hard or sharp foreign object less than 7 mm in length and if a special-risk group, as defined in the background section, is among the intended consumers of the product. The product contains a hard or sharp foreign object over 25 mm in length. A sample found to contain a foreign object that meets criterion c., d., or e., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1) if a health hazard is established by CFSAN review. The CFSAN health hazard review in this case will consider various factors including the intended use of the product, subsequent processing steps, official guidance and requirements concerning unavoidable natural defects, and other mitigating factors that could eliminate, invalidate, or neutralize the hazard prior to consumption of the food product. REMARKS: If CFSAN review finds no health hazard associated with a sample containing a hard or sharp foreign object that meets criterion c., or d., above, the sample should be considered adulterated within the meaning of *21 U.S.C. 342(a)(3)* if a CFSAN review finds the article unfit for food. The CFSAN review in this case will consider various factors including subsequent processing steps, extent of contamination, and intended use of the product. CPG 515.350 addresses imbedded objects in confectionary, which may cause such foods to be adulterated within the meaning of 21 U.S.C. 342(d)(1). SPECIMEN CHARGES: The following charges are appropriate for a product that satisfies criteria a. and b. for direct reference seizure: Article (was adulterated when introduced into and while in interstate commerce)(is adulterated while held for sale after shipment in interstate commerce), within the meaning of 21 U.S.C. 342 (a)(1), in that it bears or contains a deleterious substance which may render the food injurious to health. Article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to bear or contain a deleterious substance which may render it injurious to health. *Material between asterisks is new or revised* Issued: 3/23/1999 Revised: 5/2005

Biological Contamination Assessment

ARCOSA
SPECIALTY MATERIALS

Lisa Kosler – PCQI, Food Safety Team Leader

Summary

The following assessment is intended to determine exposure to microbiological contamination and to analyze the control measures in place and their ability to effectively identify and mitigate potential contamination hazards.

Gypsum Deposits

Gypsum is considered both a sedimentary rock and a mineral. Its chemical formula is $CaSO_4$ $2H_2O$. Gypsum was formed when ancient seas evaporated in Oklahoma during Permian time (299-251 million years ago).

There are 3 major layers of gypsum formations in Western Oklahoma. The Medicine Lodge formation is the deepest and has the purest gypsum. Arcosa Specialty Materials develops the mining pads according to how the material will be used with the Medicine Lodge layer being dedicated to the Bessie Oklahoma food grade grinding plant. Prior to mining, a pad is cleared, and core samples are obtained for testing. Samples of the Medicine Lodge deposit are collected to meet or exceed the Food and Chemical Codex specifications for food and or feed grade calcium sulfate. (See S.O.P. for sampling Food Grade Gypsum for third party testing).

In Arcosa Specialty Materials original HACCP Plan for milling calcium sulfate there were no biological concerns based on the following:

1. Low free moisture inherent in calcium sulfate
2. There is no nutritional value to support microbial growth.
3. No prior history of positive test results for pathogens in calcium sulfate.

Testing History

Production samples – Arcosa Specialty Materials has been testing for pathogens by customer request for nearly 20 years. Prior to October 2019, all results were negative for pathogens.

Pre-certification of pad samples –. In June of 2016 – the quality team began the testing at the pad development stage of the mining process. This testing included results for pathogen detection within the pad formation. From June 2016 until October 2019, every result has been negative for pathogens.

End of Lot samples – In 2019, Arcosa Specialty Materials implemented end-of-lot testing for pathogens as a confirmatory test to the pre-certification of pad samples. In October of 2019, a presumptive positive was returned for end-of-lot testing on two lot numbers. As a result, more robust preventative controls and customer disclosure program were implemented.

Trucking of gypsum rock to Bessie plant – in accordance with FSMA Sanitary Transport Rules
1. Contracted trucks dedicated to hauling gypsum rock are used to move raw material from the mine to the grinding facility.
2. Pre-loading inspection of trailer will take place at the mine and documented.
3. Receiving rock trucks inspection. (SOP)
4. Receiving packaging materials. (SOP)
5. Pre-operational inspections/checks
    Magnet checks (SOP)
    Screen checks (SOP)
    Forklift checks (SOP)
    Mill checks (SOP)
    Rock Shed check – SOP
    Loader check – SOP
6. Pre-requisite Programs
    Sanitation -Daily, Weekly and Master cleaning schedule
    Supplier Approval Program (implementing packaging supplier audits)
    Good Manufacturing Procedures (handwashing, preventive maintenance, maintenance, buildings and grounds)
    Pest Management Program
    Chemical Control Program
    Allergen Program
    Visitor Program
    Traceability Program
    Customer Complaint Program
    Recall Program
7. Customer Disclosure Program
    a. Disclosure statement provided to customer according to FSMA requirement for Preventive Controls for Human Food 21CFR117.136 and117.335 and/or 21CFR507.36 and 507.215.(Statement on COA accompanying every shipment).
    b. Annual written assurance from customer; that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard. 21CFR117.136 and117.335 and/or 21CFR507.36 and 507.215.((FDA is not requiring customers assurances currently.)

Conclusion

While it is true the potential for pathogen contamination is present, the outlined preventive controls ensure that the identified hazard will be significantly minimized or prevented.

Furthermore, the products are **Not-Ready-To-Eat** and will be further processed prior to being sold to consumers for consumption. Arcosa Specialty Materials requires customers purchasing ground calcium sulfate products for use in food or animal feed to receive and sign the Disclosure and Request for Written Assurance annually. This disclosure informs customers in writing that the product is not processed to control pathogens including Salmonella and requests written assurance that the product is processed to control pathogens in processing further downstream and complies with United States Food and Drug Administration regulations as stated in number 7 above.

ARCOSA
SPECIALTY MATERIALS

Ingredient Vulnerability Assessment – VACCP

- vulnerability to food fraud activities such as the dilution or substitution of ingredients prior to delivery to the site
- the site has appropriate controls (based on the assessment) in place to minimize the risk of purchasing fraudulent or adulterated raw materials
- all claims relating to raw materials used in products can be substantiated
- http://www.foodfraud.org/search/site - USPC Food Fraud Database

Questions with "*" "yes" answers will be V-CCP and require additional supporting documents from supplier to confirm – "No Fraud"
L = Likelihood: 1 2 3 4 5 (low to high) C = Economic Consequence: 1 2 3 4 5 (low to high)

Ingredient	Supplier	Assessment							**Likelihood**	**Economic Consequence**	**Risk = L+C**	**Is the potential food fraud reasonably likely to occur? Yes R ≥ 9 No R ≤ 8**	V-CCP yes/no
		Approved Supplier yes/no	*Supplier –History of fraud (yes/no)	Internet Search for fraud (yes/no)	*Food Fraud findings from internet search (yes/no)	*http://www.foodfraud.org/search/site	Traceable to manufacturer? (yes/no) – if not add support						
Gypsum Rock	Arcosa Specialty Materials	Y	N	Y	N	N	Y		1	1	2	NO	NO