

FarmSoy Company
96 The Farm
Summertown, TN. 38483
farmsoy@usit.net
931-964-2411 ph/fax

November 2, 2000

Keith Jones
Program Manager
National Organic Program
USDA / AMS / TM / NCP
Room 2510-South
P.O. Box 96456
Washington D.C. 20090-6456

Dear Mr. Jones and Members of NOSB,

FarmSoy Company has been a small manufacturer of soymilk and tofu since the mid 70's, and our products have been certified organic since 1995. In January of 1996, I wrote a letter (see attachment 2) , to Ted Rogers requesting that Calcium Sulfate be approved for use in processing certified organic food. I never received a reply to this request, but have recently been informed that the NOSB considered this request at an Indianapolis meeting in September 1996. Unfortunately, the NOSB concluded that it is a "synthetic substance," and prohibited its use in foods labeled 'organic.' We have traditionally used the Food and Pharmaceutical Grade of Hydrous Calcium Sulfate ($\text{CaSo}_4 \cdot 2\text{H}_2\text{O}$), also known as Calcium Sulfate Dihydrate and hydrous Terra Alba, (CAS #10101-41-4) to coagulate our soymilk to make tofu. I am writing to you today to petition that this natural substance, which is mined from the earth (see Attachment 1) near Southard Oklahoma, be included in your list of acceptable ingredients in food that is certified organic. Our company and our customers prefer the taste of tofu made with this coagulant over others, so it is important to the existence of our small company for your board to approve natural calcium sulfate as an acceptable substance to be used in the processing of foods labeled certified organic.

Natural Calcium sulfate is included on OMRI's year 2000 list of acceptable substances on page 41. In addition to attachment 1, you will find other documentation supporting the acceptability of this ingredient, including it's certification as a Kosher ingredient, a description of product and its uses, a flow chart of the manufacturing of calcium sulfate after it is mined, a certificate of analysis from the manufacturer, its MSDS, and its inclusion by the USDA on its list of "Direct food substances affirmed as GENERALLY RECOGNIZED AS SAFE."

I trust that with all of the information provided and the understanding that we are not using or requesting the approval of synthetic calcium sulfate, your committee will

easily pass this naturally occurring substance for inclusion in your list of ingredients that are acceptable for use in foods labeled 'certified organic.'

Thank you very much for your time and consideration.

Most Sincerely,

A handwritten signature in black ink that reads "Barbara L. Elliott". The signature is written in a cursive style with a large initial 'B' and 'E'.

Barbara L. Elliott
Vice President
FarmSoy Company

cc: Robert Pooler

PETITION

Calcium Sulfate, Dihydrate (Gypsum)

ITEM A

The category the substance is being petitioned for inclusion on the National List:

Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients)”.

ITEM B

1. Substance’s common name: Gypsum.
2. Manufacturers’ name, address and telephone number:

US Gypsum Company
125 South Franklin Street
Chicago, IL 60606-4678
Phone: 312-606-4000

Allied Custom Gypsum Company
PO Box 69
Lindsay, OK 73052
Phone: 405-756-9565

3. Intended or current use: In tofu making, calcium sulfate, dihydrate is used as a coagulant to precipitate soymilk protein into curd.
4. Handling activities and mode of action for the substance: Calcium sulfate, dihydrate functions as a coagulant by precipitating soymilk protein into curd form.
5. Source of the substance: Calcium sulfate, dihydrate is made by fine grinding (pulverizing) and air-separating a select, high purity mined white gypsum (calcium sulfate, dihydrate). It contains no additives.
6. Summary of previous reviews: Calcium sulfate, dihydrate is on the California organic ingredient and the previous 1995 NOSB list.
7. FDA regulatory information: Calcium sulfate is an approved additive on the FDA GRAS list of food additives (21CFR 184.1). Approvals for the use of calcium sulfate in specific food products are listed in FDA Regulations, Title 21, Food and Drugs, for enrichment, Parts 136.115 (a) 2, 137.105 (b), 137.165 (b), 137.185 (b), 137.235 (a) 3, 137.260 (a) 3, 137.305 (a) 3; for functional uses, Parts 155.170 (a) 2 xi, 150.190 (a) 2 I, 155.200 (c) 6; and for nutrient and/or dietary supplement, Part 184.1230.
8. Chemical Abstract Service (CAS) number: anhydrous [7778-18-9].

9. Substance's physical properties and chemical mode of action: Please refer to attached MSDS and product information sheets.

10. Material Safety Data Sheet (MSDS): Please refer to attached MSDS.

11. Research reviews and research bibliographies: Not available.

12. "Petition Justification Statement":

Petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance:

Calcium sulfate, dihydrate (gypsum) is a natural mined food grade mineral that has been pulverized to a very fine powder. This substance is an approved additive on the FDA Generally Recognized As Safe (GRAS) list of additives. Natural calcium sulfate, dihydrate has been used as a coagulant in tofu making for centuries.

13. Commercial Confidential Information Statement: Not Applicable.

United States Gypsum Company

Industrial Division

P.O. Box 803871

Chicago, IL 60680-3871

312 606-4000 Fax: 312 606-4519



Thank you.....

.....for requesting the enclosed information on U.S. Gypsum Company products.

If you need pricing and delivery information, or details about specific applications, please call your area Sales Representative, James Carey at 800-365-5874 x-6726.

Our Sales Representatives are available to meet with you, conduct product application seminars, demonstrate proper product usage and to provide information about our full line of products and services. It is our pleasure to serve you.

Sincerely,

UNITED STATES GYPSUM COMPANY

A handwritten signature in cursive script that reads "Loren L. Miller".

Loren L. Miller
Staff Product Manager

LLM/rc

*125 South Franklin Street
Chicago, IL 60606-4678*

A Subsidiary of USG Corporation

United States Gypsum Company _____
125 South Franklin Street _____
Chicago, IL 60606-4678 _____
(312) 606-4209 FAX: (312) 606-4519 _____
Voice Mail: (800) 365-5874 ext. 4209 _____
E-Mail: mgibbons@usg.com _____



June 23, 2000

To Whom It May Concern:

Terra Alba F&P, produced by The United States Gypsum Company, is a natural product. It is mined from high purity deposits of calcium sulfate dihydrate and pulverized. It contains no additives.

Sincerely,

A handwritten signature in cursive script, appearing to read 'MK Gibbons', followed by a horizontal line.

Martha K. Gibbons

Martha K. Gibbons
Inside Specialty Sales Representative

United States Gypsum Company

Industrial Division

P.O. Box 803871

Chicago, IL 60680-3871

312 606-4000 Fax: 312 606-4519



To Whom it May Concern:

Re: Genetically Modified Organisms

This letter certifies that USG Terra Alba and SNOW WHITE[®] Filler Food and Pharmaceutical Grade are not derived from or formulated with any genetically modified organisms (GMO).

Please contact us again if you require any additional information.

Sincerely,
UNITED STATES GYPSUM COMPANY

A handwritten signature in black ink that reads 'Susan Dichter'.

Susan Dichter
Market Sales Manager

*125 South Franklin Street
Chicago, IL 60606-4682*

A Subsidiary of USG Corporation

CHICAGO RABBINICAL COUNCIL

2701 W. Howard Street • Chicago, Illinois 60645 • (773) 465-3900
Fax • (773) 465-6632



מועצת הרבנים דשיקגו

8 Tevet 5761
3 January 2001

בס"ד

RABBI GEDALIA DOV SCHWARTZ
Av Beth Din
RABBI MOSHE KUSHNER
Administrator
RABBI DOVID JENKINS
Kashruth Administrator

TO WHOM IT MAY CONCERN:

After investigation of the raw material and processing methods employed by UNITED STATES GYPSUM COMPANY, we find that the following products are acceptable for use in kosher food products:

TERRA ALBA F&P and SNOW WHITE® F & P FILLER

These materials are made from high purity deposits of calcium sulfate dihydrate which are pulverized and contain no additives whatsoever.

These products are acceptable for kosher use for year-round including Passover.

We will review the above annually.

Rabbi Dovid Jenkins
Kashruth Administrator

DJ:rp

Calcium Sulfate for Food and Pharmaceutical Uses

USG[®] Terra Alba—F&P Grade

SNOW WHITE[®] Filler—F&P Grade

High-purity additives for high-quality products

RM0005



USG Terra Alba—F&P Grade
($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$)

SNOW WHITE Filler—F&P Grade
(CaSO_4)

USG

United States Gypsum Company

Industrial Gypsum Division

SNOW WHITE Filler-F&P Grade, because of its whiteness, is used successfully to extend TiO₂ in white cake icings at a much lower cost. This filler also functions as a stabilizer and supplies enrichment calcium.

USG Terra Alba-F&P Grade and SNOW WHITE Filler-F&P Grade are manufactured only at U.S. Gypsum's Southard, Okla. plant. Careful quality-control tests are conducted on a regular basis in a modern well-equipped laboratory. These products are *guaranteed* to meet the specifications of Food Chemicals Codex and National Formulary as 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.	10.0 ppm max.
Iron	—	100.0 ppm max.
Lead	10.0 ppm max.	—
Calcium assay	98.0% min.	98.0% min.

Upon request, U.S. Gypsum will supply a *continuing guarantee* to customers using USG Terra Alba or SNOW WHITE Filler-F&P Grade. Each shipment is batch-coded to show day, month and year of manufacture. Representative samples for reference are maintained at Southard for five years from date of shipment.

Calcium sulfate is an approved additive on the Food and Drug Administration GRAS (Generally Recognized As Safe) list of food additives. Approvals for the use of calcium sulfate in specific food products for nutritional and functional uses are listed in FDA Regulations, Title 21, Food and Drugs, Parts 1 to 199, Revised April 1, 1985 as follows:

Sections	Uses
133.111 (c) 2	With benzoyl peroxide in Caciocavallo siciliano cheese
133.141 (c) 2	With benzoyl peroxide in Gorgonzola cheese
133.165 (c) 2	With benzoyl peroxide in Parmesan and reggiano cheese
133.181 (c) 3	With benzoyl peroxide in Provolone and pasta filata cheese
133.183 (c) 2	With benzoyl peroxide in Romano cheese
133.195 (c) 1	With benzoyl peroxide in Swiss and emmentaler cheese
136.115 (a) 2	Enriched bread, rolls and buns
137.105 (a) 5	Flour
137.165 (b)	Enriched flour
137.185 (b)	Enriched self-rising flour
137.235 (a) 3	Enriched corn grits
137.260 (a) 3	Enriched corn meals
137.305 (a) 3	Enriched farina
139.115 (a) 3	Enriched macaroni products
139.117 (b) 2	Enriched macaroni products with fortified protein
139.155 (a) 3	Enriched noodle products
150.141 (a) 5	Artificially sweetened fruit jelly
150.161 (a) 5	Artificially sweetened fruit preserves and jams
155.170 (a) 2 xi	Firming agent in canned peas
155.190 (a) 2 i	Firming agent in canned tomatoes
155.200 (c) 6	Firming agent in canned potatoes
155.200 (c) 6	Firming agent in canned green sweet peppers, red sweet peppers, or lima beans
155.200 (c) 6	Firming agent in canned carrots
175.300 (xxvi)	Resinous & polymeric coatings - Pigments and colorants
178.3297	Colorants for polymers
182.90	Substances migrating to food from paper and paperboard products
184.1	GRAS
184.1230	Nutrient and/or Dietary Supplement (a) Product: Calcium Sulfate (b) Meets specifications Food Chemicals Codex (c) Anticaking, coloring, adjunct, dough strengthener, drying, firming, leavening, formulation aid, nutrient supplement, pH control, processing aid, stabilizer and thickener, synergist, and texturizer. (d) Conditions of Use: This substance is generally recognized as safe when used in accordance with good manufacturing practices. (e) Waiver—prior sanctions

Calcium sulfate is also considered safe as a migrating substance in food contact surfaces. It is acceptable for mixture with pigments and colorants used in food containers.



Use of calcium sulfate in products, processes and application is almost unlimited and is expanding every year.

USG Terra Alba and SNOW WHITE Filler—Food and Pharmaceutical Grades—meet a diversity of product requirements

USG Terra Alba-F&P Grade ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$), the *dihydrate* form of calcium sulfate, is made by fine-grinding and air-separating a select, high-purity white gypsum containing about 20% water of crystallization.

SNOW WHITE Filler-F&P Grade (CaSO_4), the *anhydrous* form of calcium sulfate, is made by high-temperature calcining of select, high-purity gypsum which is then ground and air-separated into a white powder.

In increasing volume, U.S. Gypsum Calcium Sulfate products serve the food, beverage, and pharmaceutical industries as an economical source of supplemental calcium. They are used in enriched flour and breads, cereals, baking powder, yeast foods, bread conditioners, canned vegetables and artificially sweetened jellies and preserves.

In beer manufacturing, the calcium ion, together with the needed buffering action as provided by proper water correction, promotes proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Thus, yield in the main mash is increased. In addition, the color of the wort is improved, and better precipitation and flocculation of undesirable protein complexes are achieved. The result is a paler, smoother-tasting beer with improved stability and shelf life.

For pharmaceutical applications, calcium sulfate is extensively used as a diluent serving as an excellent inert extender while it supplies dietary calcium.

Typical Analyses

	USG Terra Alba-F&P Grade	SNOW WHITE Filler-F&P Grade
Total calcium ⁽¹⁾	23.1%	29.2%
CaO	32.31%	40.92%
SO ₃	45.22%	57.46%
CaSO ₄	0.39%	97.68%
CaSO ₄ • 2H ₂ O	97.1%	—
CaCO ₃ • MgCO ₃	1.52%	0.77%
SiO ₂ and insolubles	0.24%	0.13%
Fe ₂ O ₃ • Al ₂ O ₃	0.12%	0.12%
Water loss 250 °C	20.31%	0.33%
Brightness index—min. ⁽²⁾	84.4	97.1
Oil absorption ⁽³⁾	23.5	26.5
Specific gravity	2.32	2.96
Bulk density—pcf		
Loose	42.0	44.0
Compacted	70.0	80.0
Bulking values		
Lbs. per solid gal.	19.38	24.43
Solid gals. per lb.	0.0518	0.0406
Solubility (70 °F) per 100 cc of H₂O		
	0.26 grams	0.26 grams
pH-10% slurry	7.3	10.4
Refractive index	1.52	1.56
Through 100 mesh—min.	100%	100%
Through 325 mesh—min.	93%	97%
Avg. particle size—microns	12-15	7-9

⁽¹⁾ Conversion of calcium content: Milligrams of calcium per lb. of USG Terra Alba-F&P Grade computed as follows: 1 lb. = 454 grams = 454,000 mg 23% x 454,000 mg = 104,420 mg = 1 lb. of Terra Alba-F&P Grade = 104,420 mg of calcium. Milligrams of calcium per lb. of SNOW WHITE Filler-F&P Grade computed as follows: 1 lb. = 454,000 mg 29% of 454,000 mg = 131,660 mg = 1 lb. of SNOW WHITE Filler-F&P Grade = 131,660 mg of calcium.

⁽²⁾ Brightness index was determined on a Beckman DU Spectrophotometer using magnesium oxide as the standard.

⁽³⁾ Oil absorption is the amount of linseed oil in cubic centimeters required to wet 100 grams of filler.



MATERIAL SAFETY DATA SHEET

United States Gypsum Company
125 S. Franklin Street
Chicago, IL 60606-4678

Emergency No.: (312) 606-4542
Date Issued: August 7, 1992

SECTION I

PRODUCT: Gypsum Rock and Uncalcined Ground Gypsum Products

Agricultural and Road Bed Gypsum Fines
Agricultural Gypsum
Agricultural Gypsum Coarse
Agricultural Gypsum Granular
BEN FRANKLIN* No. 1 Agricultural Gypsum
BEN FRANKLIN* Agricultural Gypsum
BEN FRANKLIN* AQUA CAL
BEN FRANKLIN* No. 420 Landplaster
Calcium Sulfate Feed Grade
Calcium Sulfate Feed Grade Coarse
Glass Batch Gypsum
HYPONEX* Lawn and Garden Gypsum
Industrial Ground Gypsum
Industrial Ground Gypsum Coarse
Industrial Ground Gypsum-White
KB Filler
SOF N-SOIL* Gypsum
US Army No. 1 Ground
USG* 500 Land Plaster

Crushed Gypsum Rock: No. 1, No. 2, No. 2A, No. 3, No. 4,
No. 5, No. 30, No. 125A Anhydrite, No. 225GA, No. 240GA,
No. 250GA, No. 260, No. 260GA, No. 350GA, No. 1 Dried Rock

* - Trademark of United States Gypsum Company or an affiliated company

CHEMICAL FAMILY: Calcium Sulfate Dihydrate

SECTION II
INGREDIENTS

MATERIAL	%	TLV mg/m3	PEL mg/m3	CAS NC.
Gypsum	80-100	10	15/5(R)	13397-24-5
Calcium Carbonate (as contaminant)	0-20	10	15/5(R)	1317-65-3

SECTION III
PHYSICAL DATA

MELTING POINT: 1450°C - decomposes
SPECIFIC GRAVITY: 2.32 - 2.96
SOLUBILITY IN WATER: 0.2%
APPEARANCE AND ODOR: Off-white to white powder or lump rock; low odor.

SECTION IV
FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (METHOD USED): None
EXTINGUISHING MEDIA: Not combustible
SPECIAL FIRE FIGHTING PROCEDURES: None
UNUSUAL FIRE AND EXPLOSION HAZARDS: None

SECTION V
HEALTH HAZARD DATA

EFFECTS OF OVEREXPOSURE:

ACUTE:

EYES: Particles may cause irritation.

SKIN: This material is not toxic. No toxic effects from powdered gypsum are noticed where air contains contaminate to excess. May dry skin.

INHALATION: Persons subjected to large amounts of this dust will be forced to leave area because of nuisance conditions such as coughing, sneezing and nasal irritation from dust.

INGESTION: None known.

CHRONIC: None known.

EMERGENCY AND FIRST AID PROCEDURES:

EYES: Flush with water to remove particles. If irritation continues, see a Physician.

SKIN: Wash with water.

INHALATION: Remove to fresh air.

INGESTION: None Known.

TARGET ORGANS: Lungs.

MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED: Pre-existing upper respiratory and lung disease such as, but not limited to, bronchitis, emphysema and asthma.

PRIMARY ROUTE OF ENTRY: Inhalation.

CARCINOGENICITY OF INGREDIENTS:

MATERIAL	IARC	NTP	OSHA
All	Not listed	Not Listed	Not Listed

SECTION VI
REACTIVITY DATA

STABILITY: Stable
INCOMPATIBILITY: Acids
HAZARDOUS DECOMPOSITION PRODUCTS: Above 1450°C - SO₂ & CaO
HAZARDOUS POLYMERIZATION: Will not occur.

SECTION VII
SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Sweep or vacuum material from spillage into a waste container for disposal. Avoid dusting conditions.

WASTE DISPOSAL METHOD: This material can be disposed of as inert solid in a landfill or by other procedures which are accepted under federal, state and local regulations.

SECTION VIII
SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: Provide general ventilation and local exhaust ventilation to meet TLV requirements. When dusty condition exists, wear an approved dust mask to guard against nuisance particles.

PROTECTIVE EQUIPMENT: Gloves or protective clothing are usually not necessary but may be desirable in specific work situations. Eye protection (goggles) may be needed to avoid particulate irritation of the eye.

SECTION IX
SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: Be sure proper ventilation and respiratory and eye protection are used under dusting conditions.

LABEL LANGUAGE:
INGREDIENTS: Contains gypsum (CAS # 13397-24-5).

CAUTION: While handling, wear a NIOSH approved dust mask. The use of safety glasses is recommended.
PRODUCT SAFETY INFORMATION: 312-606-4542
KEEP OUT OF REACH OF CHILDREN.

Attachment 1

UNITED STATES GYPSUM COMPANY
HIGHWAY 51A
PO BOX 100
SOUTHARD, OK. 73770

Tim Fox - Phone (580) 822-6156

Fax (580) 822-4501

To : Harcros Chemical, Andy Massey
Fax # (618) 344-7014

From : Tim Fox

Subject : Calcium Sulfate Food and Pharmaceutical Grade

Date 10/6/99

United States Gypsum Company located at Southard, Oklahoma produces Calcium Sulfate by surface mining the gypsum in this area. Calcium Sulfate is a natural occurring mineral and contains no synthetics or additives.


Tim Fox
Plant Chemist

trf

c:Rex Helbert

Attachment 2

FarmSoy Company
96C The Farm
Summertown, Tn. 38483
615/964-2411 phone/fax
January 3, 1996

Ted Rogers
USDA/AMS/NOP
PO Box 96456
Rm 2519 South Bldg
Washington DC 20090-6456

Dear Mr. Rogers,

The purpose of this letter is to request of your organization that the use of food/pharmaceutical grade of Calcium Sulfate be approved for use in the processing of organic food products. Although we have only been using certified Organic beans since 1992, we have used calcium sulfate for most of the 13 years that this facility has been making tofu. Our customers prefer the taste and appreciate the increased calcium content of this product.

As a small business (less than \$75,000 annual gross) struggling to survive in competition with corporate giants, we certainly hope that your organization will do everything in its power to ensure that small businesses will find Organic certification affordable and attainable.

Thank you so much for your prompt attention to this matter. I enjoyed talking with you.

Sincerely,

Barbara Elliott

Barbara Elliott
Vice-President, Secty-
Treas/Owner FarmSoy Co

Attachment 3

CHICAGO RABBINICAL COUNCIL
2701 W. Howard Street • Chicago, Illinois 60648 • (773) 485-8800
Fax • (773) 485-8632



משרד השרותים
מנהל משרד השרותים

12 Shevat 5760
12 January 2000

1" 53

RABBI GEDALIA DOV SCHWARTZ
Lv Ben Din
RABBI MENACHEM ROSENFELD
Executive Director
RABBI DAVID JENKINS
Kashruth Administrator

TO WHOM IT MAY CONCERN:

After investigation of the raw material and processing methods employed by UNITED STATES GYPSUM COMPANY, we find that the following products are acceptable for use in kosher food products:

TERRA ALBA F&P and SNOW WHITE® F & P FILLER

These materials are made from high purity deposits of calcium sulfate dihydrate which are pulverized and contain no additives whatsoever.

These products are acceptable for kosher use for year-round including Passover.

We will review the above annually.

David Jenkins
Rabbi David Jenkins
Kashruth Administrator

DJ:rp

United States Gypsum Company
P.O. Box 100, Highway 51A
Southard, Ok. 73770-0100
(580) 522-8168

Attachment 4

USG

CERTIFICATE OF ANALYSIS

TERRA ALBA
(HYDROUS CALCIUM SULFATE · CaSO₄·2H₂O)
Food & Pharmaceutical Grade

Faxed: 9/18/2000

TO : Harcros Chemical, Westbrook, Me
ATTN: Carol Bonister, FAX #: (207) 844-8878
FROM : Tim Fox, United States Gypsum, Box 100, Southard, Ok. 73770

Lot No : 0621008 Refer No : Lab Refer : 5 Ship Date :
Tons : BULK:

REMARKS : FOOD & CHEMICAL CODEX = HEAVY METALS AS LEAD
Terra Alba will process best if used by 12/18/2000

**FOOD & PHARMACEUTICAL GRADE
ANALYSIS**

AA Graphite Furnace
Lead (ppm) : < 0.35 Arsenic (ppm) : < 0.48 Selenium (ppm) : < 30 Iron (ppm) : < 36.20
EDTA Titration Ion Select Electrode Computrac
CaSO₄ Assay (%) : 99.92 Fluoride (ppm) : < 30 LOD (%) : 20.15

PHYSICAL ANALYSIS

% Passing Alpine Jet Sieve : -100 MESH = 99.96 -325 MESH = 95.00
(Particle Fineness)

Tim Fox
Tim Fox, Chemist

FCC & NATIONAL FORMULARY SPECIFICATIONS

Lead-- 10 ppm max Iron-- 100 ppm max Arsenic-- 3 ppm max Selenium-- 30 ppm max.
CaSO₄ Assay -- 98.0% min Fluoride -- 30 ppm max. LOD (% Wt. Loss) - 18% min.

PHYSICAL SPECIFICATIONS

Alpine Jet Sieve Specification: -100 = 99.95% min. -325 = 93% min.



CONTROLLED COPY
IF THIS PRINT IS IN RED

C: 982-6, S. Dichter
227-QL035

REV. 000

EFFECTIVE DATE : 03/25/97

APPROVED BY: TIM FOX

Attachment
5

USG Terra Alba and Snow White Filler—Food and Pharmaceutical Grades—meet a diversity of product requirements

USG Terra Alba-F&P Grade ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$), the dihydrate form of calcium sulfate, is made by fine-grinding and air-separating a select, high-purity white gypsum containing about 20% water of crystallization.

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Typical Analyses

	USG Terra Alba-F&P Grade	SNOW WHITE Filler-F&P Grade
Total calcium ¹⁾	23.1%	29.2%
CaO	32.31%	40.92%
SO ₃	45.22%	57.46%
CaSO ₄	0.39%	97.68%
CaSO ₄ • 2H ₂ O	97.1%	—
CaSO ₄ • MgSO ₄	1.52%	0.77%
SiO ₂ and insolubles	0.24%	0.13%
Fe ₂ O ₃ • Al ₂ O ₃	0.12%	0.12%
Water less 250 °C	20.81%	0.33%
Brightness index—min. ²⁾	84.4	97.1
Oil absorption ³⁾	23.5	26.5
Specific gravity	2.32	2.96
Bulk density—pcf		
Loose	42.0	44.0
Compacted	70.0	80.0
Bulking values		
Lbs. per solid gal.	19.38	24.43
Solid gals. per lb.	0.0513	0.0406
Solubility (70 °F) per 100 cc of H ₂ O	0.26 grams	0.26 grams
pH-10% slurry	7.3	10.4
Refractive index	1.52	1.56
Through 100 mesh—min.	100%	100%
Through 200 mesh—min.	93%	97%
Avg. particle size—microns	12-15	7-9

¹⁾ Conversion of total calcium content: Milligrams of calcium per lb. of USG Terra Alba-F&P Grade computed as follows: 1 lb. = 454 grams = 454,000 mg 12% x 454,000 mg = 104,420 mg. 1 lb. of Terra Alba-F&P Grade = 104,420 mg of calcium. Milligrams of calcium per lb. of Snow White Filler-F&P Grade computed as follows: 1 lb. = 454,000 mg 29% of 454,000 mg = 131,660 mg. 1 lb. of Snow White Filler-F&P Grade = 131,660 mg of calcium.

²⁾ Brightness index was determined on a Beckman DU Spectrophotometer using magnesium oxide as the standard.

³⁾ Oil absorption is the amount of linseed oil in cubic centimeters required to wet 100 grams of filler.



SNOW WHITE Filler-F&P Grade, because of its whiteness, is used successfully to extend TiO_2 in white cake icings at a much lower cost. This filler also functions as a stabilizer and supplies enrichment calcium.

USG Terra Alba-F&P Grade and SNOW WHITE Filler-F&P Grade are manufactured only at U.S. Gypsum's Southard, Okla. plant. Careful quality-control tests are conducted on a regular basis in a modern well-equipped laboratory. These products are *guaranteed* to meet the specifications of Food Chemicals Codex and National Formulary as 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.	10.0 ppm max.
Iron	—	100.0 ppm max.
Lead	10.0 ppm max.	—
Calcium assay	98.0% min.	98.0% min.

Upon request, U.S. Gypsum will supply a *continuing guarantee* to customers using USG Terra Alba or SNOW WHITE Filler-F&P Grade. Each shipment is batch-coded to show day, month and year of manufacture. Representative samples for reference are maintained at Southard for five years from date of shipment.

Calcium sulfate is an approved additive on the Food and Drug Administration GRAS (Generally Recognized As Safe) list of food additives. Approvals for the use of calcium sulfate in specific food products for nutritional and functional uses are listed in FDA Regulations, Title 21, Food and Drugs, Parts 1 to 199, Revised April 1, 1985 as follows:

Sections	Uses
133.111 (c) 2	With benzoyl peroxide in Caciocavallo siciliano cheese
133.141 (c) 2	With benzoyl peroxide in Gorgonzola cheese
133.165 (c) 2	With benzoyl peroxide in Parmesan and reggiano cheese
133.181 (c) 3	With benzoyl peroxide in Provolone and pasta filata cheese
133.183 (c) 2	With benzoyl peroxide in Romano cheese
133.195 (c) 1	With benzoyl peroxide in Swiss and emmentaler cheese
136.115 (a) 2	Enriched bread, rolls and buns
*97.105 (a) 5	Flour
137.165 (b)	Enriched flour
137.165 (b)	Enriched self-rising flour
137.235 (a) 3	Enriched corn grits
137.260 (a) 3	Enriched corn meals
137.305 (a) 3	Enriched farina
139.115 (a) 3	Enriched macaroni products
139.117 (b) 2	Enriched macaroni products with fortified protein
139.155 (a) 3	Enriched noodle products
150.141 (a) 5	Artificially sweetened fruit jelly
150.161 (a) 5	Artificially sweetened fruit preserves and jams
155.170 (a) 2 XI	Firming agent in canned peas
155.190 (a) 2 I	Firming agent in canned tomatoes
155.200 (c) 6	Firming agent in canned potatoes
155.200 (c) 6	Firming agent in canned green sweet peppers, red sweet peppers, or lima beans
155.200 (c) 6	Firming agent in canned carrots
175.300 (xxvi)	Resinous & polymeric coatings - Pigments and colorants
178.3297	Colorants for polymers
182.80	Substances migrating to food from paper and paperboard products
184.1	GRAS
184.1230	Nutrient and/or Dietary Supplement (a) Product: Calcium Sulfate (b) Meets specifications Food Chemicals Codex (c) Anticaking, coloring, adjunct, dough strengthener, drying, firming, leavening, formulation aid, nutrient supplement, pH control, processing aid, stabilizer and thickener, synergist, and texturizer. (d) Conditions of Use: This substance is generally recognized as safe when used in accordance with good manufacturing practices. (e) Waiver—prior sanctions

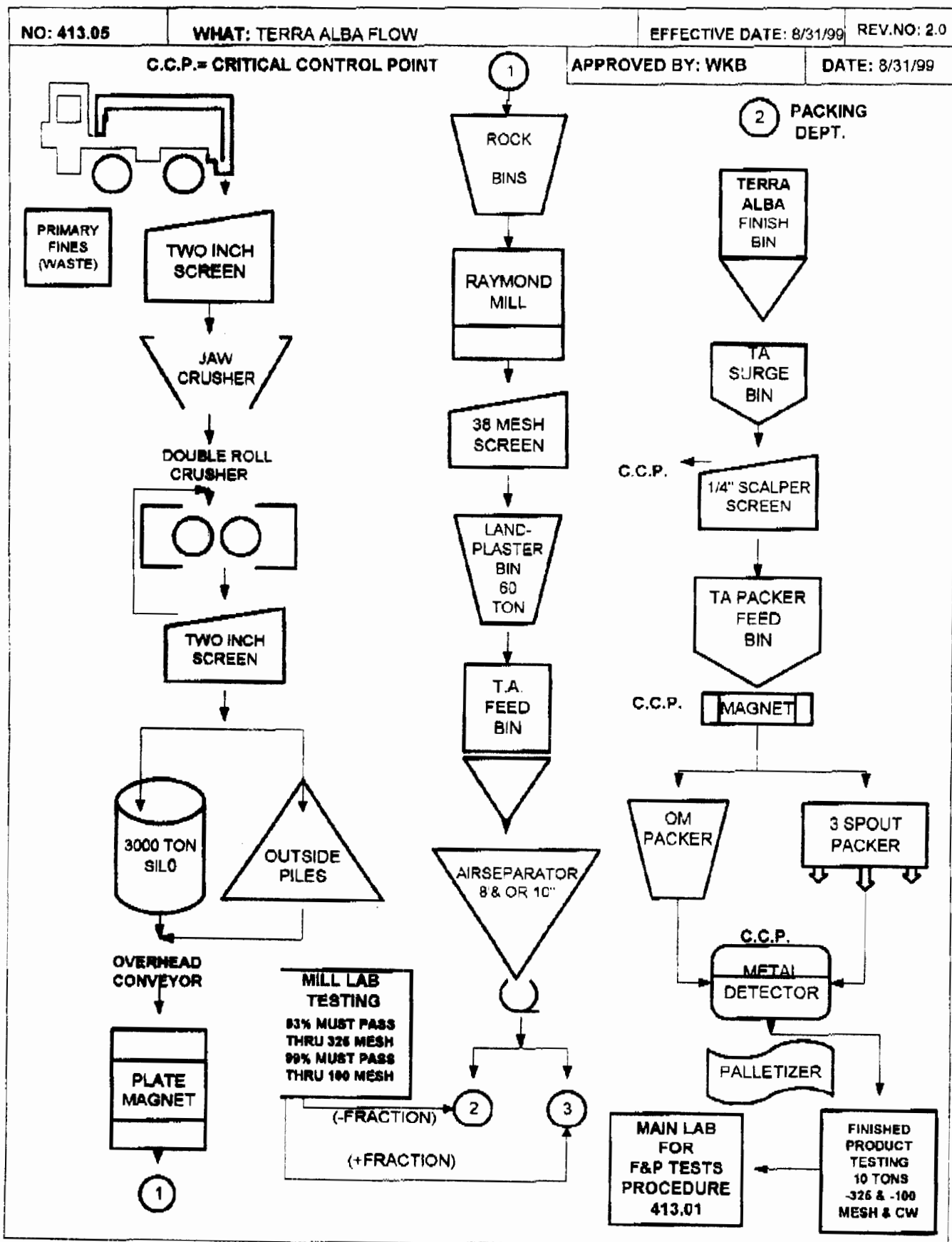
Calcium sulfate is also considered safe as a migrating substance in food contact surfaces. It is acceptable for mixture with pigments and colorants used in food containers.



Use of calcium sulfate in products, processes and application is almost

QUALITY (MAIN LAB) PROCEDURE

Attachment 6



Attachment 7

**MATERIAL SAFETY DATA SHEET**

MSDS NO 05052

USG® Terra Alba F & P

Page 1 of 3

United States Gypsum Company
125 South Franklin Street
Chicago, Illinois 60606-4678

Product Safety: 1 (800) 507-8899
Version Date: October 1, 1999
Version 3

SECTION I PRODUCT IDENTIFICATION

PRODUCT: USG® Terra Alba F & P**CHEMICAL FAMILY:** Gypsum (Calcium Sulfate Dihydrate, $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$)

SECTION II INGREDIENTS

MATERIAL	%	TLV (mg/m ³)	PEL (mg/m ³)	CAS NUMBFR
Gypsum	90-98	10	15(T)/5(R)	13397-24-5
Limestone	0-10	10	15(T)/5(R)	1317-6b-3
Crystalline Silica	<5	0.1(R)	0.1(R)	14808-60-7

(T) = Total (R) = Respirable

All ingredients of this product are included in the U.S. Environmental Protection Agency's Toxic Substances Control Act Chemical Substance Inventory. All components of this product are included in the Canadian Domestic Substances List (DSL) or the Canadian Non-Domestic Substances List (NDSL).

INFORMATION FOR HANDLING AND IDENTIFICATION OF CHEMICAL HAZARDS

NFPA Ratings: Health: 0 Fire: 0 Reactivity: 0 Other: N/A
HMIS Ratings: Health: 0 Fire: 0 Reactivity: 0
Personal Protection: Use eye and skin protection. Use NIOSH/MSHA-approved respiratory protection when necessary
0 = Minimal Hazard 1 = Slight Hazard 2 = Moderate Hazard 3 = Serious Hazard 4 = Severe Hazard

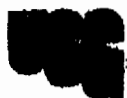
SECTION III PHYSICAL DATA

Appearance and Odor: Off white to white powder; low odor
Melting Point: 1450°C - decomposes
Specific Gravity: 2.32 - 2.96
Solubility in Water: 0.26%

SECTION IV FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not combustible
Extinguishing Media: Use extinguishing media appropriate for surrounding fire.
Special Fire Fighting Procedures: None
Unusual Fire and Explosion Hazards: None

SECTION V HEALTH HAZARD DATA



MATERIAL SAFETY DATA SHEET

USG® Terra Alba F & P

MSDS NO. 05052

Page 2 of 3

This product can release nuisance dust in handling or during use. Eye, skin, nose, throat and upper respiratory irritation can occur with dust exposure.

EFFECTS OF OVEREXPOSURE:

ACUTE:

EYES: Direct contact can cause mechanical (particulate) irritation of eyes. If burning, redness, itching, pain or other symptoms persist or develop, consult physician.

SKIN: No toxic effects from powdered gypsum are noticed where air contains contaminate to excess. This material exhibits some affinity for moisture, and frequent exposures may have a drying effect on the skin. Possible itching and irritation may be experienced. This may lead to dermatitis.

INHALATION: Inhalation of dusts from this product may irritate the nose, throat, lungs, and upper respiratory tract. Persons subjected to large amounts of this dust will be forced to leave area because of nuisance conditions such as coughing, sneezing and nasal irritation. If respiratory symptoms persist, consult physician.

INGESTION: This product is gypsum. Gypsum is non-toxic, however, ingestion of a sufficient quantity could lead to mechanical obstruction of the gut, especially the pyloric region.

CHRONIC:

INHALATION: None known for gypsum. Prolonged and repeated exposure to respirable crystalline silica can result in lung disease (i.e., silicosis) and/or lung cancer.

EMERGENCY AND FIRST AID PROCEDURES:

EYES: Flush thoroughly with water for 15 minutes to remove particles. If irritation persists, consult physician.

SKIN: Wash with mild soap and water. A commercially available hand lotion may be used to treat dry skin areas. If skin has become cracked, take appropriate action to prevent infection and promote healing.

INHALATION: Leave the area of dust exposure and remain away until coughing and other symptoms subside. Other measures are usually not necessary, however, if conditions warrant, call physician.

INGESTION: Ingestion of sufficient quantity may result in mechanical obstruction of the gut. If there is any discomfort, consult physician.

TARGET ORGANS: Eyes, skin, lungs, and respiratory system.

MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED: Pre-existing upper respiratory and lung disease such as, but not limited to, bronchitis, emphysema and asthma.

PRIMARY ROUTES OF ENTRY: Inhalation, eyes, and skin contact.

CARCINOGENICITY OF INGREDIENTS:

MATERIAL	IARC	NTP
Crystalline Silica	Group 1	Anticipated

In June, 1987, the International Agency for Research on Cancer (IARC) classified crystalline silica (quartz and cristobalite) as a human carcinogen. In making the overall evaluation, the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Carcinogenicity may be dependent on inherent characteristics of the crystalline silica or on external factors affecting its biological activity or distribution of its polymorphs.

IARC states that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1).

SECTION VI REACTIVITY DATA

STABILITY:	Stable
INCOMPATIBILITY:	Acids
HAZARDOUS POLYMERIZATION:	Will not occur.
HAZARDOUS DECOMPOSITION:	Above 1450°C could produce SO ₂ & CaO



MATERIAL SAFETY DATA SHEET

USG® Terra Alba F & P

MSDS NO. 05052

Page 3 of 3

SECTION VII

HAZARD PRECAUTIONS

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Avoid creating excessive dust. Wear appropriate protective equipment. Scoop up material from spillage into a waste container for disposal, or if not contaminated by foreign material it may be reclaimed for processing.

WASTE DISPOSAL METHOD:

Dispose of in accordance with local, state and federal regulations.

SECTION VIII

EXPOSURE CONTROLS AND PERSONAL PROTECTION

RESPIRATORY PROTECTION:

Not typically necessary under normal conditions of use. Avoid inhalation of dust. Dust created from mixing or handling may cause eye, nose, throat or upper respiratory irritation. Wear a NIOSH/MSHA-approved dust respirator if TLV is exceeded and/or when dusty conditions exist. Provide general ventilation and/or local exhaust ventilation to meet TLV requirements.

PROTECTIVE EQUIPMENT:

Gloves or protective clothing are usually not necessary but may be desirable in specific work situations. Wear adequate clothing to minimize drying of skin. Wear safety glasses or goggles for eye protection to avoid particulate irritation of the eye.

SECTION IX

PHYSIOLOGICAL EFFECTS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:

Store in a dry place. Minimize exposures in accordance with good industrial hygiene practice. During handling wear the appropriate respiratory, eye and skin protection if warranted per environmental conditions.

CAUTION!

Dust may cause eye, skin, nose, throat or upper respiratory irritation. Avoid inhalation of dust and eye contact. Provide good general ventilation and/or local exhaust to reduce dust exposure. If dusty conditions exist, use NIOSH/MSHA-approved respiratory protection. Wear eye protection to avoid particulate irritation of eye. If eye contact occurs, flush thoroughly with water for 15 minutes. If irritation persists, call physician. Product safety information (800) 507-8899.

KEEP OUT OF REACH OF CHILDREN

END

code of federal regulations

Food and Drugs

Attachment 8

21

PARTS 170 TO 199

Revised as of April 1, 1994

**CONTAINING
A CODIFICATION OF DOCUMENTS
OF GENERAL APPLICABILITY
AND FUTURE EFFECT**

AS OF APRIL 1, 1994

With Ancillaries

Published by
the Office of the Federal Register
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Administration

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the Federal Register





United States Gypsum Company
Highway 51A
Southard, OK 73770

Telefax: (580) 822-4501

[Code of Federal Regulations]
[Title 21, Volume 3, Parts 170 to 199]
[Revised as of April 1, 2000]
From the U.S. Government Printing Office v
[CITE: 21CFR184.1230]

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[Page 484]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

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

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1230 Calcium sulfate.

(a) Calcium sulfate (CaSO₄, CAS Reg. No. 7778-18-9 or ~~CaSO₄2H₂O, 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as an anticaking agent as defined in Sec. 170.3(o)(1) of this chapter, color and coloring adjunct as defined in Sec. 170.3(o)(4) of this chapter, dough strengthener as defined in Sec. 170.3(o)(6) of this chapter, drying agent as defined in Sec. 170.3(o)(7) of this chapter, firming agent as defined in Sec. 170.3(o)(10) of this chapter, flour treating agent as defined in Sec. 170.3(o)(13) of this chapter, formulation aid as defined in Sec. 170.3(o)(14) of this chapter, leavening agent as defined in Sec. 170.3(o)(17) of this chapter, nutrient supplement as defined in Sec. 170.3(o)(20) of this chapter, pH control agent as defined in Sec. 170.3(o)(23) of this chapter, processing aid as defined in Sec. 170.3(o)(24) of this chapter, stabilizer and thickener as defined in Sec. 170.3(o)(28) of this chapter, synergist as defined in Sec. 170.3(o)(31) of this chapter, and texturizer as defined in Sec. 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 Sec. 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 Sec. 170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in Sec. 170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in Sec. 170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in Sec. 170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in Sec. 170.3(n)(23) of this chapter, 0.35 percent for processed vegetables as defined in Sec. 170.3(n)(35) 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. 16, 1980, as amended at 45

Source: 42 FR 1463, Mar. 16, 1977, unless otherwise noted.

Support A—General Provisions

§ 194.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this part shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS. Ingredients affirmed as GRAS in this part are also GRAS as listed in human food ingredients, subject to any limitations prescribed in parts 174, 175, 176, 177, 178 or 179 of this chapter or 176, 177, 178 or 179 of this chapter. The party in part 186 of this chapter, do not apply specifications in this part, do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with § 170.30(b)(1) of this chapter.

(b) Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practices. For the purpose of this part, current good manufacturing practices include the requirements that a direct human food ingredient be of approved grade; that it be prepared and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technological effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practices, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraph (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe

use or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of those limited conditions of use, which may include the category of food(s) of use, the technological effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that use of an ingredient is GRAS may submit a GRAS petition in accordance with § 170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS. (4) The labeling of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(5) The labeling of more than one ingredient to produce the same technological effect does not authorize a combination of two or more ingredients to accomplish the same technological effect in any one food at a level greater than the highest level permitted for one of the ingredients.

Support B—Listing of Specific Substances Affirmed as GRAS

§ 194.1005 Acetic acid.

(a) Acetic acid (CH₃CO₂H, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from butane, and liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient means the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20543, or available for inspection at the Office of the Federal Register, 500 North Capitol Street, NW, suite 700, Washington, DC 20540.

(c) The ingredient is used as a curing and pickling agent as defined in § 170.30(x)(5) of this chapter. Flavor enhancer as defined in § 170.30(x)(1) of this chapter; flavoring agent and additive as defined in § 170.30(x)(2) of this chapter; pH control agent as defined in § 170.30(x)(3) of this chapter; as a solvent and vehicle as defined in § 190.30(x)(22) of this chapter; and as a boiler water additive complying with § 173.350 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practices in accordance with § 194.1(b)(2). Current good manufacturing practices result in a maximum level as set forth, of 0.25 percent for banded goods as defined in § 170.30(x)(1) of this chapter; 0.8 percent for cheeses as defined in § 170.30(x)(5) of this chapter and dairy product analogs as defined in § 170.30(x)(10) of this chapter; 0.5 percent for chewing gum as defined in § 170.30(x)(9) of this chapter; 0.9 percent for confections and relishes as defined in § 170.30(x)(8) of this chapter; 0.5 percent for fats and oils as defined in § 170.30(x)(12) of this chapter; 2.0 percent for gravies and sauces as defined in § 170.30(x)(25) of this chapter; 0.6 percent for meat products as defined in § 170.30(x)(26) of this chapter; and 0.15

(4) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will comment on such use in the regulation covering such use of the ingredient under part 181 of this chapter. If the Commissioner is unaware of any such regulation or if he is aware of any such regulation but does not intend to assert proof of its existence, any regulation promulgated pursuant to this section shall include a determination that exclusion of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a violation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(1) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 181 of this chapter. (2) A statement of concentration of the ingredient in any intermediate mix or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

(4) FR 1463, Mar. 16, 1977, as amended at 42 FR 5439, Oct. 14, 1977; 42 FR 9927, 9928, Oct. 19, 1977.

(b) The acid or with regulations prescribed under section 412(a)(3) of the Act. (4) Prior sanctions for this ingredient in this section do not exist or have been waived.

§ 164.1213 Calcium propionate

(a) Calcium propionate (C₉H₁₆CaO₄, CAS Reg. No. 4075-81-4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

§ 164.1214 Calcium pantothenate

(a) Calcium pantothenate (C₁₂H₁₈CaO₁₀, CAS Reg. No. of the D-isomer, 137-08-6) is a salt of pantoic acid, one of the vitamins of the B complex. Only the D-isomer of pantoic acid has vitamin activity, although both the D-isomer and the D-eremic mixture of calcium pantothenate are used in food. Commercial calcium pantothenate is prepared synthetically from isobutyraldehyde and hydroxy-propionalddehyde and pantothenate.

§ 164.1215 Calcium pantothenate

(a) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1961), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Inspector, 800 North Capitol Street, NW., rule 700, Washington, DC 20004.

§ 164.1216 Calcium pantothenate

(a) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1961), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Inspector, 800 North Capitol Street, NW., rule 700, Washington, DC 20004.

§ 164.1217 Calcium pantothenate

(a) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1961), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Inspector, 800 North Capitol Street, NW., rule 700, Washington, DC 20004.

§ 164.1218 Calcium pantothenate

(a) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1961), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Inspector, 800 North Capitol Street, NW., rule 700, Washington, DC 20004.

§ 164.1219 Calcium pantothenate

(a) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1961), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Inspector, 800 North Capitol Street, NW., rule 700, Washington, DC 20004.

Food, and Drug Administration, HHS

§ 164.1229 Calcium stearate

(a) Calcium stearate (Ca(C₁₇H₃₅COO)₂, CAS Reg. No. 1550-22-9) is the calcium salt of stearic acid derived from edible sources. It is prepared as a white precipitate by mixing calcium chloride and sodium stearate in aqueous solution.

§ 164.1230 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1231 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1232 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1233 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1234 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1235 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1236 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

§ 164.1237 Calcium sulfite

(a) Calcium sulfite (CaSO₃, CAS Reg. No. 778-35-2 or CaSO₃·2H₂O, CAS Reg. No. 10301-41-4), also known as plaster of Paris, analytical, 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 500° C. In an electric oven.

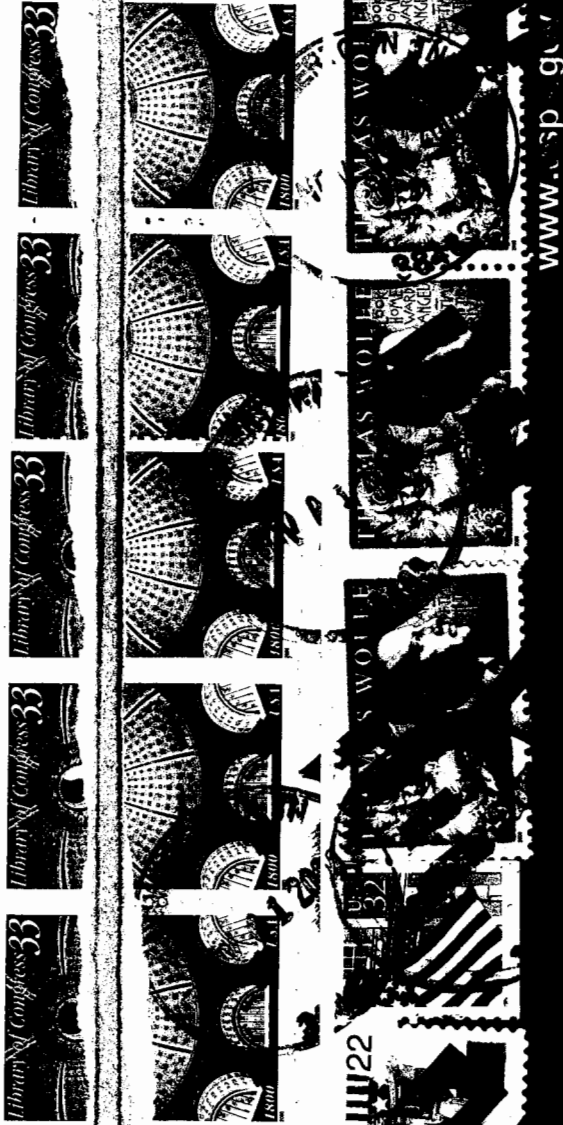
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July 22

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2. PAYMENT METHOD

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3. ATTACH LABEL (if provided)

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FARMISOY

96 THE FARM SUMMERTOWN, TN 38483

original

Keith Jones, Program MGR
 National Organic Program
 USDA/AMS/TM/NCP
 Room 2510 - South
 P.O. Box 96456
 Washington DC
 20090-6456

ATTN: NOSB Ingredient Petition

The efficient FLAT RATE ENVELOPE.

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August 22, 2001

Soy milk, Beverages, Tofu, Oriental Pasta, and Specialty Items

National Organics Standards Board
c/o Mr. Robert Pooler
Agricultural Specialist
USDA/AMS/TM/NOP
Room 2510-So., Ag Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

RE: NOP Petition for Calcium Sulfate

Dear Mr. Pooler:

Vitasoy applauds the USDA's efforts for responsibly directing the guidelines for establishing a National Organic Program. The process of reviewing materials for qualification and inclusion on the national list must be challenging.

Vitasoy USA Inc. is in general support of the National Organic Program (NOP) on the USDA proposed organic standard. A leading producer and marketer of soy foods, Vitasoy USA Inc has manufactured organic soy based products such as tofu and soy drink for more than fifteen years.

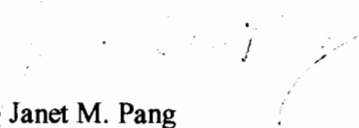
Reviewing the list of nonsynthetic materials allowed under the non-agricultural (non-organic) substances (7 CFR Subpart G, Section 205.605), we noticed that Calcium Sulfate, Dihydrate (gypsum) was perhaps inadvertently omitted. We understand that naturally occurring substances are allowed, unless prohibited.

Calcium Sulfate, dihydrate is a naturally occurring nonagricultural substance that should be approved for use in organic foods. We strongly recommend that the NOP consider adding this ingredient when finalizing the regulation. Attached is a petition for Calcium Sulfate to be reviewed by the National Organic Standards board.

The attached document serves as a petition for the inclusion of natural Calcium Sulfate, Dihydrate on the National List of nonsynthetic or nonagricultural substance.

Should you have questions concerning this matter, please do not hesitate to contact me at (415) 285-1130 Ext. 203 or e-mail me at: janet.pang@vitasoy-usa.com.

Sincerely,


Janet M. Pang
R&D Manager
VITASOY USA INC.

cc: Marian Casazza –VP of Quality Systems, Quality Assurance International.
Nancy Chapman - Executive Director, Soyfoods Association of North America
Katherine DiMatteo – Executive Director, Organic Trade Association

Labeling % Organic Disk\Vitasoy Petition to NOP – August 13, 2001.doc

A Z U M A Y A • N A S O Y A • N E W M E N U • V I T A • V I T A S O Y • 維他奶 • 維他山奶

Petition for Calcium Sulfate, dihydrate (gypsum)
From Vitasoy USA Inc., South San Francisco, CA

Page 1

PETITION

Calcium Sulfate, Dihydrate (Gypsum)

ITEM A

The category the substance is being petitioned for inclusion on the National List:

Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients)”.

ITEM B

1. Substance’s common name: Gypsum.
2. Manufacturers’ name, address and telephone number:

US Gypsum Company
125 South Franklin Street
Chicago, IL 60606-4678
Phone: 312-606-4000

Allied Custom Gypsum Company
PO Box 69
Lindsay, OK 73052
Phone: 405-756-9565

3. Intended or current use: In tofu making, calcium sulfate, dihydrate is used as a coagulant to precipitate soymilk protein into curd.
4. Handling activities and mode of action for the substance: Calcium sulfate, dihydrate functions as a coagulant by precipitating soymilk protein into curd form.
5. Source of the substance: Calcium sulfate, dihydrate is made by fine grinding (pulverizing) and air-separating a select, high purity mined white gypsum (calcium sulfate, dihydrate). It contains no additives.
6. Summary of previous reviews: Calcium sulfate, dihydrate is on the California organic ingredient and the previous 1995 NOSB list.
7. FDA regulatory information: Calcium sulfate is an approved additive on the FDA GRAS list of food additives (21CFR 184.1). Approvals for the use of calcium sulfate in specific food products are listed in FDA Regulations, Title 21, Food and Drugs, for enrichment, Parts 136.115 (a) 2, 137.105 (b), 137.165 (b), 137.185 (b), 137.235 (a) 3, 137.260 (a) 3, 137.305 (a) 3; for functional uses, Parts 155.170 (a) 2 xi, 150.190 (a) 2 I, 155.200 (c) 6; and for nutrient and/or dietary supplement, Part 184.1230.
8. Chemical Abstract Service (CAS) number: anhydrous [7778-18-9].

9. Substance's physical properties and chemical mode of action: Please refer to attached MSDS and product information sheets.

10. Material Safety Data Sheet (MSDS): Please refer to attached MSDS.

11. Research reviews and research bibliographies: Not available.

12. "Petition Justification Statement":

Petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance:

Calcium sulfate, dihydrate (gypsum) is a natural mined food grade mineral that has been pulverized to a very fine powder. This substance is an approved additive on the FDA Generally Recognized As Safe (GRAS) list of additives. Natural calcium sulfate, dihydrate has been used as a coagulant in tofu making for centuries.

13. Commercial Confidential Information Statement: Not Applicable.

United States Gypsum Company

Industrial Division

P.O. Box 803871

Chicago, IL 60680-3871

312 606-4000 Fax: 312 606-4519



Thank you.....

.....for requesting the enclosed information on U.S. Gypsum Company products.

If you need pricing and delivery information, or details about specific applications, please call your area Sales Representative, James Carey at 800-365-5874 x-6726.

Our Sales Representatives are available to meet with you, conduct product application seminars, demonstrate proper product usage and to provide information about our full line of products and services. It is our pleasure to serve you.

Sincerely,

UNITED STATES GYPSUM COMPANY

A handwritten signature in cursive script that reads 'Loren L. Miller'.

Loren L. Miller
Staff Product Manager

LLM/rc

*125 South Franklin Street
Chicago, IL 60606-4678*

A Subsidiary of USG Corporation

United States Gypsum Company _____
125 South Franklin Street _____
Chicago, IL 60606-4678 _____
(312) 606-4209 FAX: (312) 606-4519 _____
Voice Mail: (800) 365-3874 ext. 4209 _____
E-Mail: mgibbons@usg.com _____



June 23, 2000

To Whom It May Concern:

Terra Alba F&P, produced by The United States Gypsum Company, is a natural product. It is mined from high purity deposits of calcium sulfate dihydrate and pulverized. It contains no additives.

Sincerely,

A handwritten signature in black ink, appearing to read 'MK Gibbons', with a long horizontal flourish extending to the right.

Martha K. Gibbons

Martha K. Gibbons
Inside Specialty Sales Representative

United States Gypsum Company

Industrial Division

P.O. Box 803871

Chicago, IL 60680-3871

312 606-4000 Fax: 312 606-4519



To Whom it May Concern:

Re: Genetically Modified Organisms

This letter certifies that USG Terra Alba and SNOW WHITE[®] Filler Food and Pharmaceutical Grade are not derived from or formulated with any genetically modified organisms (GMO).

Please contact us again if you require any additional information.

Sincerely,
UNITED STATES GYPSUM COMPANY

A handwritten signature in cursive script that reads "Susan Dichter".

Susan Dichter
Market Sales Manager

125 South Franklin Street
Chicago, IL 60606-4682

A Subsidiary of USG Corporation

CHICAGO RABBINICAL COUNCIL

2701 W. Howard Street • Chicago, Illinois 60645 • (773) 465-3900
Fax • (773) 465-6632



מועצת הרבנים דשיקגו

8 Tevet 5761
3 January 2001

כס"ד

RABBI GEDALIA DOV SCHWARTZ
Av Beth Din
RABBI MOSHE KUSHNER
Administrator
RABBI DOVID JENKINS
Kashruth Administrator

TO WHOM IT MAY CONCERN:

After investigation of the raw material and processing methods employed by UNITED STATES GYPSUM COMPANY, we find that the following products are acceptable for use in kosher food products:

TERRA ALBA F&P and SNOW WHITE® F & P FILLER

These materials are made from high purity deposits of calcium sulfate dihydrate which are pulverized and contain no additives whatsoever.

These products are acceptable for kosher use for year-round including Passover.

We will review the above annually.

Rabbi Dovid Jenkins
Kashruth Administrator

DJ:rp

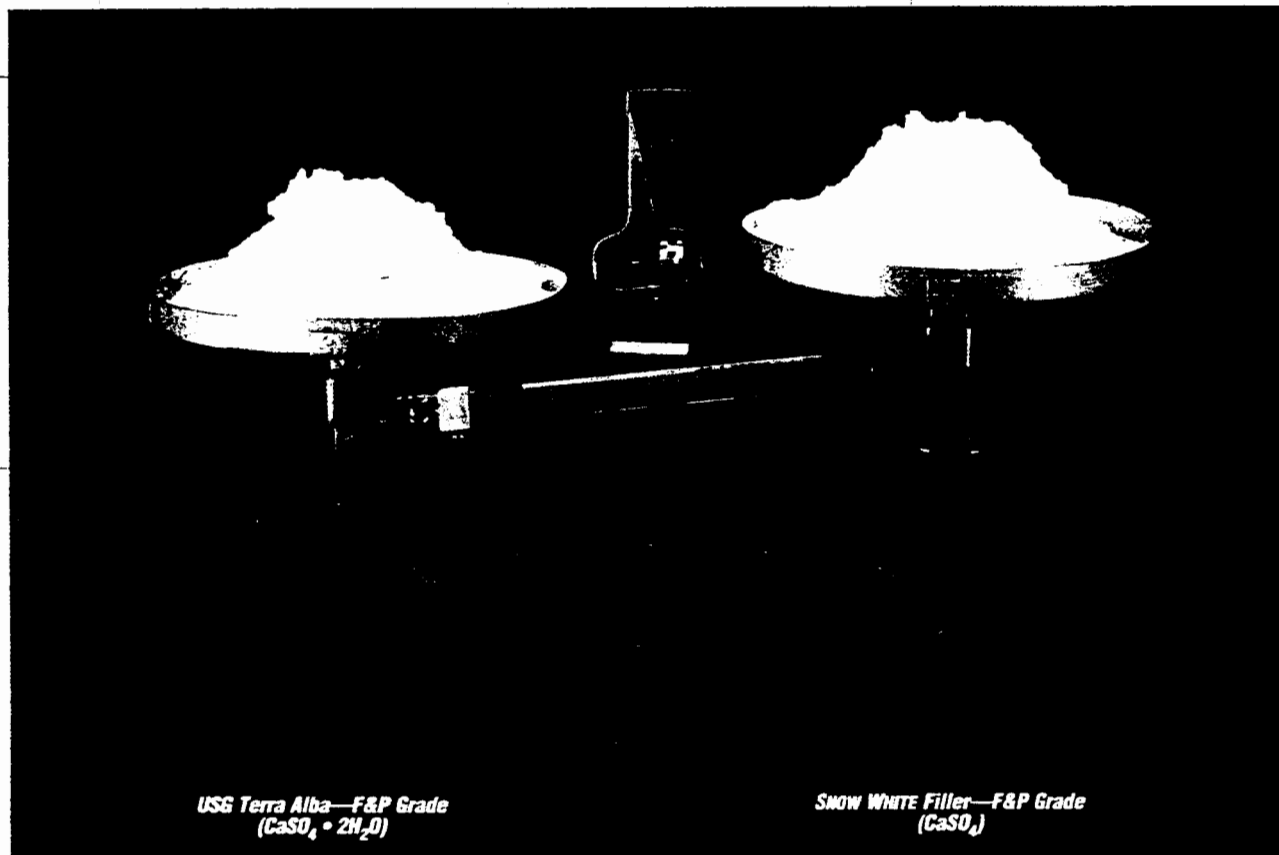
Calcium Sulfate for Food and Pharmaceutical Uses

RM0065

USG[®] Terra Alba—F&P Grade

SNOW WHITE[®] Filler—F&P Grade

High-purity additives for high-quality products



United States Gypsum Company

Industrial Gypsum Division

SNOW WHITE Filler-F&P Grade, because of its whiteness, is used successfully to extend TiO_2 in white cake icings at a much lower cost. This filler also functions as a stabilizer and supplies enrichment calcium.

USG Terra Alba-F&P Grade and SNOW WHITE Filler-F&P Grade are manufactured only at U.S. Gypsum's Southard, Okla. plant. Careful quality-control tests are conducted on a regular basis in a modern well-equipped laboratory. These products are *guaranteed* to meet the specifications of Food Chemicals Codex and National Formulary as 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.	10.0 ppm max.
Iron	—	100.0 ppm max.
Lead	10.0 ppm max.	—
Calcium assay	98.0% min.	98.0% min.

Upon request, U.S. Gypsum will supply a *continuing guarantee* to customers using USG Terra Alba or SNOW WHITE Filler-F&P Grade. Each shipment is batch-coded to show day, month and year of manufacture. Representative samples for reference are maintained at Southard for five years from date of shipment.

Calcium sulfate is an approved additive on the Food and Drug Administration GRAS (Generally Recognized As Safe) list of food additives. Approvals for the use of calcium sulfate in specific food products for nutritional and functional uses are listed in FDA Regulations, Title 21, Food and Drugs, Parts 1 to 199, Revised April 1, 1985 as follows:

Sections	Uses
133.111 (c) 2	With benzoyl peroxide in Caciocavallo siciliano cheese
133.141 (c) 2	With benzoyl peroxide in Gorgonzola cheese
133.165 (c) 2	With benzoyl peroxide in Parmesan and reggiano cheese
133.181 (c) 3	With benzoyl peroxide in Provolone and pasta filata cheese
133.183 (c) 2	With benzoyl peroxide in Romano cheese
133.195 (c) 1	With benzoyl peroxide in Swiss and emmentaler cheese
136.115 (a) 2	Enriched bread, rolls and buns
137.105 (a) 5	Flour
137.165 (b)	Enriched flour
137.185 (b)	Enriched self-rising flour
137.235 (a) 3	Enriched corn grits
137.260 (a) 3	Enriched corn meals
137.305 (a) 3	Enriched farina
139.115 (a) 3	Enriched macaroni products
139.117 (b) 2	Enriched macaroni products with fortified protein
139.155 (a) 3	Enriched noodle products
150.141 (a) 5	Artificially sweetened fruit jelly
150.161 (a) 5	Artificially sweetened fruit preserves and jams
155.170 (a) 2 xi	Firming agent in canned peas
155.190 (a) 2 i	Firming agent in canned tomatoes
155.200 (c) 6	Firming agent in canned potatoes
155.200 (c) 6	Firming agent in canned green sweet peppers, red sweet peppers, or lima beans
155.200 (c) 6	Firming agent in canned carrots
175.300 (xxvi)	Resinous & polymeric coatings - Pigments and colorants
178.3297	Colorants for polymers
182.90	Substances migrating to food from paper and paperboard products
184.1	GRAS
184.1230	Nutrient and/or Dietary Supplement (a) Product: Calcium Sulfate (b) Meets specifications Food Chemicals Codex (c) Anticaking, coloring, adjunct, dough strengthener, drying, firming, leavening, formulation aid, nutrient supplement, pH control, processing aid, stabilizer and thickener, synergist, and texturizer. (d) Conditions of Use: This substance is generally recognized as safe when used in accordance with good manufacturing practices. (e) Waiver—prior sanctions

Calcium sulfate is also considered safe as a migrating substance in food contact surfaces. It is acceptable for mixture with pigments and colorants used in food containers.



Use of calcium sulfate in products, processes and applications is almost unlimited and is expanding every year.

USG Terra Alba and SNOW WHITE Filler—Food and Pharmaceutical Grades—meet a diversity of product requirements

USG Terra Alba-F&P Grade ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$), the *dihydrate* form of calcium sulfate, is made by fine-grinding and air-separating a select, high-purity white gypsum containing about 20% water of crystallization.

SNOW WHITE Filler-F&P Grade (CaSO_4), the *anhydrous* form of calcium sulfate, is made by high-temperature calcining of select, high-purity gypsum which is then ground and air-separated into a white powder.

In increasing volume, U.S. Gypsum Calcium Sulfate products serve the food, beverage, and pharmaceutical industries as an economical source of supplemental calcium. They are used in enriched flour and breads, cereals, baking powder, yeast foods, bread conditioners, canned vegetables and artificially sweetened jellies and preserves.

In beer manufacturing, the calcium ion, together with the needed buffering action as provided by proper water correction, promotes proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Thus, yield in the main mash is increased. In addition, the color of the wort is improved, and better precipitation and flocculation of undesirable protein complexes are achieved. The result is a paler, smoother-tasting beer with improved stability and shelf life.

For pharmaceutical applications, calcium sulfate is extensively used as a diluent serving as an excellent inert extender while it supplies dietary calcium.

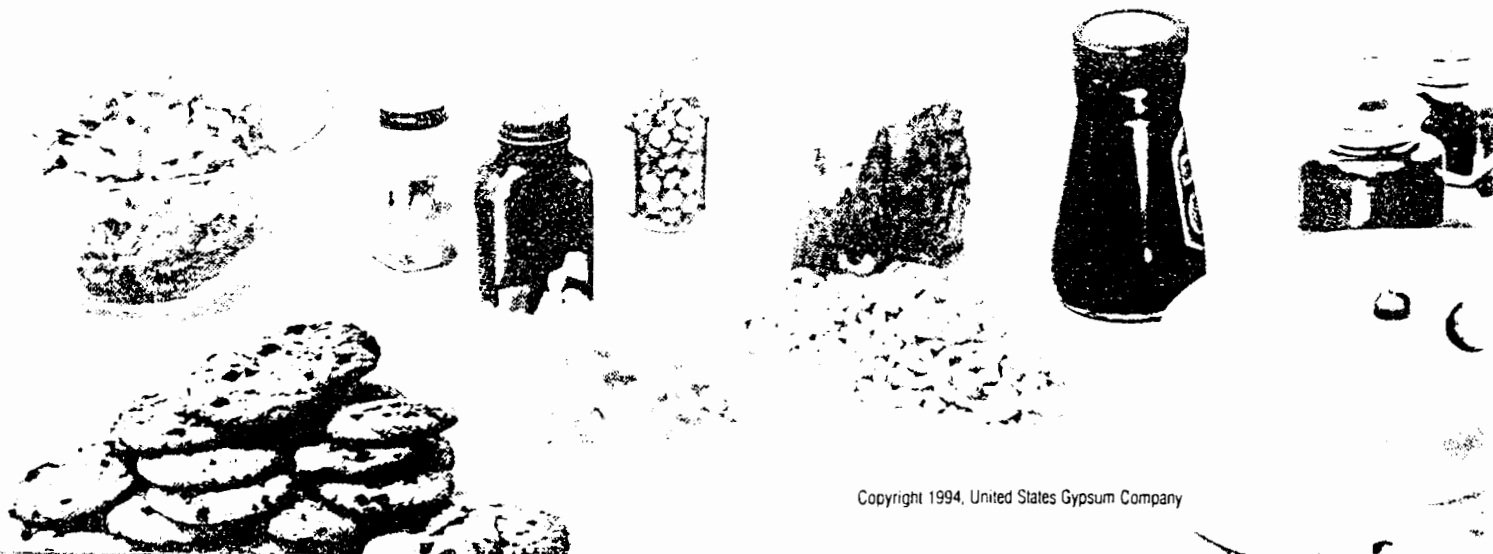
Typical Analyses

	USG Terra Alba-F&P Grade	SNOW WHITE Filler-F&P Grade
Total calcium⁽¹⁾	23.1%	29.2%
CaO	32.31%	40.92%
SO₃	45.22%	57.46%
CaSO₄	0.39%	97.68%
CaSO₄ • 2H₂O	97.1%	—
CaCO₃ • MgCO₃	1.52%	0.77%
SiO₂ and insolubles	0.24%	0.13%
Fe₂O₃ • Al₂O₃	0.12%	0.12%
Water loss 250 °C	20.31%	0.33%
Brightness index—min.⁽²⁾	84.4	97.1
Oil absorption⁽³⁾	23.5	26.5
Specific gravity	2.32	2.96
Bulk density—pcf		
Loose	42.0	44.0
Compacted	70.0	80.0
Bulking values		
Lbs. per solid gal.	19.38	24.43
Solid gals. per lb.	0.0518	0.0406
Solubility (70 °F) per 100 cc of H₂O	0.26 grams	0.26 grams
pH-10% slurry	7.3	10.4
Refractive index	1.52	1.56
Through 100 mesh—min.	100%	100%
Through 325 mesh—min.	93%	97%
Avg. particle size—microns	12-15	7-9

⁽¹⁾ Conversion of calcium content: Milligrams of calcium per lb. of USG Terra Alba-F&P Grade computed as follows: 1 lb. = 454 grams = 454,000 mg 23% x 454,000 mg = 104,420 • 1 lb. of Terra Alba-F&P Grade = 104,420 mg of calcium. Milligrams of calcium per lb. of SNOW WHITE Filler-F&P Grade computed as follows: 1 lb. = 454,000 mg 29% of 454,000 mg = 131,660 mg • 1 lb. of SNOW WHITE Filler-F&P Grade = 131,660 mg of calcium.

⁽²⁾ Brightness index was determined on a Beckman DU Spectrophotometer using magnesium oxide as the standard.

⁽³⁾ Oil absorption is the amount of linseed oil in cubic centimeters required to wet 100 grams of filler.



MATERIAL SAFETY DATA SHEET

United States Gypsum Company
125 S. Franklin Street
Chicago, IL 60606-4678

Emergency No.: (312) 606-4542
Date Issued: August 7, 1992

SECTION I

PRODUCT: Gypsum Rock and Uncalcined Ground Gypsum Products

Agricultural and Road Bed Gypsum Fines
Agricultural Gypsum
Agricultural Gypsum Coarse
Agricultural Gypsum Granular
BEN FRANKLIN* No. 1 Agricultural Gypsum
BEN FRANKLIN* Agricultural Gypsum
BEN FRANKLIN* AQUA CAL
BEN FRANKLIN* No. 420 Landplaster
Calcium Sulfate Feed Grade
Calcium Sulfate Feed Grade Coarse
Glass Batch Gypsum
HYPONEX* Lawn and Garden Gypsum
Industrial Ground Gypsum
Industrial Ground Gypsum Coarse
Industrial Ground Gypsum-White
KB Filler
SOF N-SOIL* Gypsum
US Army No. 1 Ground
USG* 500 Land Plaster

Crushed Gypsum Rock: No. 1, No. 2, No. 2A, No. 3, No. 4,
No. 5, No. 30, No. 125A Anhydrite, No. 225GA, No. 240GA,
No. 250GA, No. 260, No. 260GA, No. 350GA, No. 1 Dried Rock

* - Trademark of United States Gypsum Company or an affiliated company

CHEMICAL FAMILY: Calcium Sulfate Dihydrate

SECTION II
INGREDIENTS

MATERIAL	%	TLV mg/m3	PEL mg/m3	CAS NC.
Gypsum	80-100	10	15/5(R)	13397-24-5
Calcium Carbonate (as contaminant)	0-20	10	15/5(R)	1317-65-3

SECTION VI
REACTIVITY DATA

STABILITY: Stable
INCOMPATIBILITY: Acids
HAZARDOUS DECOMPOSITION PRODUCTS: Above 1450°C - SO₂ & CaO
HAZARDOUS POLYMERIZATION: Will not occur

SECTION VII
SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Sweep or vacuum material from spillage into a waste container for disposal. Avoid dusting conditions.

WASTE DISPOSAL METHOD: This material can be disposed of as inert solid in a landfill or by other procedures which are accepted under federal, state and local regulations.

SECTION VIII
SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION: Provide general ventilation and local exhaust ventilation to meet TLV requirements. When dusty condition exists, wear an approved dust mask to guard against nuisance particles.

PROTECTIVE EQUIPMENT: Gloves or protective clothing are usually not necessary but may be desirable in specific work situations. Eye protection (goggles) may be needed to avoid particulate irritation of the eye.

SECTION IX
SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: Be sure proper ventilation and respiratory and eye protection are used under dusting conditions.

LABEL LANGUAGE:
INGREDIENTS: Contains gypsum (CAS # 13397-24-5).

CAUTION: While handling, wear a NIOSH approved dust mask. The use of safety glasses is recommended.
PRODUCT SAFETY INFORMATION: 312-606-4542
KEEP OUT OF REACH OF CHILDREN.



United States
Department of
Agriculture

Agricultural
Marketing
Service

Transportation
and
Marketing

P.O. Box 96456
Washington, DC
20090-6456

November 30, 2001

Ms. Janet M. Pang
Vitasoy USA Inc.
1575 Burke Avenue
San Francisco, California 94124

Dear Ms. Pang:

Thank you for your petition of August 30, 2001, which proposes the addition of Calcium sulfate to the National Organic Program's (NOP) National List of Allowed and Prohibited Substances (National List). The status of your petition is as marked below.

_____ Your petition has been accepted for review by the National Organic Standards Board (NOSB) and tentatively scheduled for consideration by the NOSB at its (date) meeting. No additional action on your part is needed at this time. You may monitor the status of your petition at the NOP website (www.ams.usda.gov/nop).

_____ Your petition is returned because the NOSB has determined that the petition is incomplete. Specifically, information is required for item(s) () of the enclosed document titled "Information to be Included in a Petition."

X Your petition is returned because it requests the addition of a substance previously reviewed by the NOSB on March 6, 2001. At that time, the NOSB approved the substance for recommendation to the Secretary of Agriculture for inclusion onto the National List.

_____ Your petition is returned because it requests action on a formulated product. Active ingredients and inert ingredients must be individually petitioned for addition to the National List.



The Agricultural Marketing Service
is an agency of the
United States Department of Agriculture

Janet M. Pang
Page 2

If you have questions regarding this notification, please feel free to call me at (202) 720-3252.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Pooler". The signature is fluid and cursive, with a large initial "R" and a long horizontal stroke at the end.

Robert Pooler, Agricultural Marketing Specialist
National Organic Program

cc: Kim Burton, Chair
NOSB Materials Committee

Enclosure:



August 22, 2001

Soy milk, Beverages, Tofu, Oriental Pasta, and Specialty Items

National Organics Standards Board
c/o Mr. Robert Pooler
Agricultural Specialist
USDA/AMS/TM/NOP
Room 2510-So., Ag Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

RE: NOP Petition for Calcium Sulfate

Dear Mr. Pooler:

Vitasoy applauds the USDA's efforts for responsibly directing the guidelines for establishing a National Organic Program. The process of reviewing materials for qualification and inclusion on the national list must be challenging.

Vitasoy USA Inc. is in general support of the National Organic Program (NOP) on the USDA proposed organic standard. A leading producer and marketer of soy foods, Vitasoy USA Inc has manufactured organic soy based products such as tofu and soy drink for more than fifteen years.

Reviewing the list of nonsynthetic materials allowed under the non-agricultural (non-organic) substances (7 CFR Subpart G, Section 205.605), we noticed that Calcium Sulfate, Dihydrate (gypsum) was perhaps inadvertently omitted. We understand that naturally occurring substances are allowed, unless prohibited.

Calcium Sulfate, dihydrate is a naturally occurring nonagricultural substance that should be approved for use in organic foods. We strongly recommend that the NOP consider adding this ingredient when finalizing the regulation. Attached is a petition for Calcium Sulfate to be reviewed by the National Organic Standards board.

The attached document serves as a petition for the inclusion of natural Calcium Sulfate, Dihydrate on the National List of nonsynthetic or nonagricultural substance.

Should you have questions concerning this matter, please do not hesitate to contact me at (415) 285-1130 Ext. 203 or e-mail me at: janet.pang@vitasoy-usa.com.

Sincerely,

Janet M. Pang
R&D Manager
VITASOY USA INC.

cc: Marian Casazza –VP of Quality Systems, Quality Assurance International.
Nancy Chapman - Executive Director, Soyfoods Association of North America
Katherine DiMatteo – Executive Director, Organic Trade Association

Labeling % Organic Disk\Vitasoy Petition to NOP – August 13, 2001.doc

A Z U M A Y A • N A S O Y A • N E W M E N U • V I T A • V I T A S O Y • 維他奶 • 維他山奶

Calcium
Sulfate

CaSO₄ TABLE
TAP
NL Petition

Pooler, Bob

From: K. Downey, OMRI [kdowney@omri.org]
Sent: Friday, February 09, 2001 3:30 PM
To: dailyblessing@yc2.net; tmarkking72@hotmail.com; wfof@means.net; goldie@pccsea.com; dave.carter@rmfu.org; rosiesfarm@mindspring.com; jriddle@luminet.net; george.simon@organicvalley.com; cwbrickey@aol.com; kim.burton@jmsmucker.com; becky@edf.org; steven.harper@smallplanetfoods.com; willie.lockeretz@tufts.edu; esideman@mofga.org; obandele@su.jags.subr.edu; obandel@aol.com; Jones, Keith; Pooler, Bob; bb@omri.org; ebr@omri.org
Cc:
Subject: cal sulfate table--again



CaSO₄-Tab4-b3 final.doc

Dear NOSB members:

I just e-mailed out the table that accompanies the calcium sulfate TAP review, but it appears to not have been sent correctly. It is attached here, again.

Sincerely,
Kathleen Downey, OMRI Executive Director

The uses and potential substitutes for calcium sulfate in processing systems depend on the specific purpose for using the material. Calcium sulfate has a wide variety of food uses, with the main functions and products summarized in Table 4. (EAFUS, 2001 and 27 CFR 24.246). Of the uses mentioned, calcium sulfate should only be considered for some, as the others would be disqualified under criteria used by the TAP. Each of these uses/functions will be considered individually in this section, as its necessity/essentiality and compatibility in organic production, and potential alternatives (organic or otherwise):

Table 4
Reviewer 1 Commentary on Uses

Use/function	Products	Reviewer 1 Comments:	Alternatives
Firming agent	mainly canned fruits and vegetables	Not compatible, as the calcium sulfate would only be used to recreate texture lost during processing, or “improve” texture not had in the first place.	Grape leaves, cherry leaves, other fruit or oak leaves, for certain applications such as pickling. Salts already included on the National List.
Dough conditioner	Breads, crackers, other baked items	Not compatible or essential, as calcium sulfate is being used to improve a texture that could be otherwise achieved via alternative baking techniques. Not a necessary ingredient for any baked goods formulation.	Salt; skillful baking techniques.
Yeast food	Beer and other fermentation products	Not necessary, as there are a variety of organic ingredients which can be substrates for this purpose.	Organic foodstuffs as substrates
pH adjuster, flocculating agent, calcium source	Beer brewing, winemaking	1) As an aid in beer brewing, use of calcium sulfate purportedly increases yield when it is added to the mash tun. Supposedly it also increases yield by promoting proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Although the increase in yield is favorable to the brewer, it is not essential to the process. 2) Water adjustment is said by some brewers to often be necessary to provide a flavor and finish that is needed, particularly with top-fermented yeast. Calcium stimulates enzyme activity and improves protein digestion, stabilizes the alpha amylase, helps gelatinize starch and improves lauter runoff. While sulfates can impart off-flavors, so can chloride (salty) and carbonate (chalky). Calcium also extracts fine bittering principles of the hop and reduces wort color.	Various, depending on the process and product.
Coloring/bleaching agent	Cheeses, flours	Not compatible, as calcium sulfate is being used to alter a color without any other purpose. Not a necessary ingredient.	Food without colorants
Carrier for bleaching agent	Cereal flours	Not compatible, as color alteration is not a valid use for organic.	Unbleached flour
Jelling agent	fruit jellies	Not compatible, as other more suitable alternatives exist, and it is most often used with artificially sweetened jellies and preserves.	Pectins
Abrasive	Toothpaste, tooth powders	Not really applicable at this time for organic considerations. Alternatives exist.	Calcium carbonate

The uses and potential substitutes for calcium sulfate in processing systems depend on the specific purpose for using the material. Calcium sulfate has a wide variety of food uses, with the main functions and products summarized in Table 4. (EAFUS, 2001 and 27 CFR 24.246). Of the uses mentioned, calcium sulfate should only be considered for some, as the others would be disqualified under criteria used by the TAP. Each of these uses/functions will be considered individually in this section, as its necessity/essentiality and compatibility in organic production, and potential alternatives (organic or otherwise):

Table 4
Reviewer 1 Commentary on Uses

Use/function	Products	Reviewer 1 Comments:	Alternatives
Firming agent	mainly canned fruits and vegetables	Not compatible, as the calcium sulfate would only be used to recreate texture lost during processing, or "improve" texture not had in the first place.	Grape leaves, cherry leaves, other fruit or oak leaves, for certain applications such as pickling. Salts already included on the National List.
Dough conditioner	Breads, crackers, other baked items	Not compatible or essential, as calcium sulfate is being used to improve a texture that could be otherwise achieved via alternative baking techniques. Not a necessary ingredient for any baked goods formulation.	Salt; skillful baking techniques.
Yeast food	Beer and other fermentation products	Not necessary, as there are a variety of organic ingredients which can be substrates for this purpose.	Organic foodstuffs as substrates
pH adjuster, flocculating agent, calcium source	Beer brewing, winemaking	1) As an aid in beer brewing, use of calcium sulfate purportedly increases yield when it is added to the mash tun. Supposedly it also increases yield by promoting proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Although the increase in yield is favorable to the brewer, it is not essential to the process. 2) Water adjustment is said by some brewers to often be necessary to provide a flavor and finish that is needed, particularly with top-fermented yeast. Calcium stimulates enzyme activity and improves protein digestion, stabilizes the alpha amylase, helps gelatinize starch and improves lauter runoff. While sulfates can impart off-flavors, so can chloride (salty) and carbonate (chalky). Calcium also extracts fine bittering principles of the hop and reduces wort color.	Various, depending on the process and product.
Coloring/bleaching agent	Cheeses, flours	Not compatible, as calcium sulfate is being used to alter a color without any other purpose. Not a necessary ingredient.	Food without colorants
Carrier for bleaching agent	Cereal flours	Not compatible, as color alteration is not a valid use for organic.	Unbleached flour
Jelling agent	fruit jellies	Not compatible, as other more suitable alternatives exist, and it is most often used with artificially sweetened jellies and preserves.	Pectins
Abrasive	Toothpaste, tooth powders	Not really applicable at this time for organic considerations. Alternatives exist.	Calcium carbonate

Pooler , Bob

From: K. Downey, OMRI [kdowney@omri.org]
Sent: Friday, February 09, 2001 2:57 PM
To: dailyblessing@yc2.net%inter2; /DDV=tmarkking72@hot
mail.com.wfof@means.net/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=goldie@pccsea.com.lynn.eschbach@rmfu.org/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=rosiesfarm@mindspring.com.jriddle@luminet.net/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=george.simon@organicvalley.com.cwbrickey@aol.com/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=kim.burton@jmsmucker.com.becky@edf.org/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=steven.harper@smallplanetfoods.com.wlockertz@infonet.tufts.edu/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US;/DDV=esideman@mofga.org.obandele@su.jags.subr.edu/DDT=RFC-822/O=INTER2/P=GOV+USDA/A=ATTMAIL/C=US; obandel@aol.com%inter2
Cc: Jones, Keith; Pooler , Bob; bb@omri.org%inter2; ebr@omri.org%inter2
Subject: cal sulfate Table



Ca504-Tab4-b3 final.doc

Dear NOSB members:

This attachment is the table that accompanies the calcium sulfate TAP review.

Sincerely,
Kathleen Downey, OMRI Executive Director

The uses and potential substitutes for calcium sulfate in processing systems depend on the specific purpose for using the material. Calcium sulfate has a wide variety of food uses, with the main functions and products summarized in Table 4. (EAFUS, 2001 and 27 CFR 24.246). Of the uses mentioned, calcium sulfate should only be considered for some, as the others would be disqualified under criteria used by the TAP. Each of these uses/functions will be considered individually in this section, as its necessity/essentiality and compatibility in organic production, and potential alternatives (organic or otherwise):

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Dough conditioner	Breads, crackers, other baked items	Not compatible or essential, as calcium sulfate is being used to improve a texture that could be otherwise achieved via alternative baking techniques. Not a necessary ingredient for any baked goods formulation.	Salt; skillful baking techniques.
Yeast food	Beer and other fermentation products	Not necessary, as there are a variety of organic ingredients which can be substrates for this purpose.	Organic foodstuffs as substrates
pH adjuster, flocculating agent, calcium source	Beer brewing, winemaking	<ol style="list-style-type: none"> 1) As an aid in beer brewing, use of calcium sulfate purportedly increases yield when it is added to the mash tun. Supposedly it also increases yield by promoting proper gelatinization of the starch in the cooker mash, as well as protein degradation and starch conversion. Although the increase in yield is favorable to the brewer, it is not essential to the process. 2) Water adjustment is said by some brewers to often be necessary to provide a flavor and finish that is needed, particularly with top-fermented yeast. Calcium stimulates enzyme activity and improves protein digestion, stabilizes the alpha amylase, helps gelatinize starch and improves lauter runoff. While sulfates can impart off-flavors, so can chloride (salty) and carbonate (chalky). Calcium also extracts fine bittering principles of the hop and reduces wort color. 	Various, depending on the process and product.
Coloring/bleaching agent	Cheeses, flours	Not compatible, as calcium sulfate is being used to alter a color without any other purpose. Not a necessary ingredient.	Food without colorants
Carrier for bleaching agent	Cereal flours	Not compatible, as color alteration is not a valid use for organic.	Unbleached flour
Jelling agent	fruit jellies	Not compatible, as other more suitable alternatives exist, and it is most often used with artificially sweetened jellies and preserves.	Pectins
Abrasive	Toothpaste, tooth powders	Not really applicable at this time for organic considerations. Alternatives exist.	Calcium carbonate

1000
2250 Harrison St 18-11
Alb, Or 97001

PLACE STICKER AT TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS
FOLD AT DOTTED LINE
CERTIFIED MAIL



7000 1670 0008 3290 8139



9254

20090

\$4
0005



National Organic Stds Board

% Robert Pooler

Agricultural Marketing Specialist

USDA/Ams/Tm/NOF, Room 2510-50

Ag Stop 0268

P.O. Box 96456

Washington D.C.

20090-6456

NOSB NATIONAL LIST FILE CHECKLIST

PROCESSING

MATERIAL NAME: #1 Calcium sulfite



NOSB Database Form



References



MSDS (or equivalent)



FASP (FDA)



TAP Reviews from: Joe Montecalvo, Rich
Theuer, Steve Taylor,
William Zimmer, Walter
Jeffery

**NOSB/NATIONAL LIST
COMMENT FORM
PROCESSING**

Material Name: #1 Calcium sulfate

Please use this page to write down comments, questions, and your anticipated vote(s).

COMMENTS/QUESTIONS:

1. In my opinion, this material is:
_____ Synthetic _____ Non-synthetic.

2. Should this material be allowed in an “organic food” (95% or higher organic ingredients)? _____ Yes _____ No
(IF NO, PROCEED TO QUESTION 3.)

3. Should this substance be allowed in a “food made with organic ingredients” (50% or higher organic ingredients)? _____ Yes _____ No

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Calcium Sulfate

Reviewer Name: William A. Zimmer D.V.M. RECEIVED JUL 30 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

non-synthetic - commonly found natural mined ore
If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed Prohibited Natural

or, Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or, this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

Large reserves of calcium sulfate (gypsum) exist which are byproducts of industrial processing. These should not be allowed for organic use due to contamination with numerous potentially toxic substances - solvents, etc.

Please comment on the accuracy of the information in the file:

Properties - naturally occurring gray, white ores

Type of Use - soil nutrient, amendment providing calcium and sulfur.

Any additional comments? (attachments welcomed)

Information currently limited to processing only!

Do you have a commercial interest in this material? Yes; No

Signature William A. Zimmer D.V.M. Date 7/8/96

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

As Soil nutrient - none

As Animal nutrient - minimal, excessive feeding levels could produce a sulfate excess. Under the anaerobic conditions of the digestive tract hydrogen sulfide gas could be formed. No detrimental actions if fed at normal dietary rates.

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

none - toxic compounds could only arise from contaminants added to calcium sulfate as byproducts of industrial processing

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance; none - land application provides usable plant nutrients

- (4) the effect of the substance on human health;

Not Applicable

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

Source of soil nutrients - calcium and sulfur, generally considered to improve soil tilth, biological activity and soil productivity. Source of available crop nutrients. source of available livestock nutrients.

- (6) the alternatives to using the substance in terms of practices or other available materials; and combinations of other sulfur or calcium containing compounds. eg. calcium carbonate, calcium oxide, potassium sulfate, magnesium sulfate, elemental sulfur. as nutrient source

- (7) its compatibility with a system of sustainable agriculture.

very compatible

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Calcium Sulfate

Reviewer Name: R C Theuer RECEIVED AUG 05 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate) SYNTHETIC

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed Prohibited Natural

or, Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or, this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

Please comment on the accuracy of the information in the file:

ADEQUATE

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? Yes; No

Signature R C Theuer Date 8/5/96

USDA/TAP REVIEWER
COMMENT FORM

Mailing date: 1 Jul 1996.

Due date: 5 Aug 1996

Name of Materials: Calcium Sulfate, Food Grade
Reviewer Name: Richard C. Theuer

SYNTHETIC: The natural mineral "gypsum" is calcium sulfate. However, for food use the purity requirements demand a synthetic material made by reacting calcium hydroxide with sulfuric acid. Both calcium hydroxide and sulfuric acid are synthetic materials, so their reaction product, calcium sulfate, is synthetic as well.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Inhalation of calcium sulfate dust is the only real hazard with this material.
 2. Calcium is an essential nutrient, the level of which must be labeled in the Nutrition Facts box. Calcium sulfate is relative insoluble but has some bioavailability.
 3. Calcium sulfate (gypsum) is used to treat clay soils so the relatively small amounts of calcium sulfate used in foods would not represent a hazard to soil microorganisms or crops.
-

The following synthetic substance should be allowed as an ingredient in organic foods. It should be added to the National List of synthetic substances allowed for use as ingredients or processing aids in Organic Food:

calcium sulfate

August 5, 1996

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Calcium Sulfate

Reviewer Name: Steve Taylor RECEIVED AUG 05 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

If synthetic, how is the material made? (please answer here if our database form is blank)

I do not know how this substance is made so will abstain

This material should be added to the National List as:

Synthetic Allowed Prohibited Natural

or, Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or, this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

Please comment on the accuracy of the information in the file:

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? Yes; No

Signature Steve Taylor Date 8/5/96

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

Virtually none

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

Calcium sulfate is a nutrient source for Ca; toxicity observed only at very high doses.

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

Virtually none

- (4) the effect of the substance on human health;

Beneficial effect ~~from~~ as source of calcium

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

N/A

- (6) the alternatives to using the substance in terms of practices or other available materials; and

Other calcium salts

- (7) its compatibility with a system of sustainable agriculture.

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Calcium Sulfate

Reviewer Name: JOE MONTECALVO RECEIVED AUG 05 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Synthetic
If synthetic, how is the material made? (please answer here if our database form is blank) Seed database

This material should be added to the National List as:
 Synthetic Allowed Prohibited Natural
or, Non-synthetic (Allowed as an ingredient in organic food)
 Non-synthetic (Allowed as a processing aid for organic food)
or, this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?
- should only be used as a firming agent for canned vegetables general: < 0.1%

Please comment on the accuracy of the information in the file:
good

Any additional comments? (attachments welcomed)
NONE

Do you have a commercial interest in this material? Yes; No

Signature [Signature] Date 7/27/96

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

None

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

None

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

None

- (4) the effect of the substance on human health;

- consumption on a regular basis may lead to intestinal obstruction

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

None

- (6) the alternatives to using the substance in terms of practices or other available materials; and

None

- (7) its compatibility with a system of sustainable agriculture.

OK.

Identification

Common Name: Calcium Sulfate Chemical Name:
Other Names:
Code #: CAS Reg. No. 7778-18-9 Code #: Other
N. L. Category MSDS yes no

Chemistry

Family:
Composition: $CaSO_4 \cdot xH_2O$ $CaSO_4$ OR $CaSO_4 \cdot 2H_2O$
Properties: Calcium sulfate is anhydrous or contains two molecules of water of hydration. It occurs as a fine, white to slightly yellow white, odorless powder.
How Made: - From natural sources and as a byproduct in many chemical operations.
GRAPE - technical and pure precipitated as the dihydrate

Use/Action

Type of Use: Processing
Specific Use(s): Nutrient; dietary supplement; yeast food; dough conditioner; firming agent; sequestrant. - in brewing
Action:
Combinations: (in canned tomatoes) Sweet peppers, etc. potatoes

Status

OFPA
N. L. Restriction
EPA, FDA, etc
Directions
Safety Guidelines
Historical status
International status

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

2119(m)5: agroecosystem biology

2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

References

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Calcium Sulfate

Reviewer Name: WALTER JEFFERY RECEIVED JUL 29 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

non-synthetic if mined product
If synthetic, how is the material made? (please answer here if our database form is blank)
Anhydrite, gypsum and hemihydrate are mined products. Some synthetic gypsum is produced from stack gas scrubbing or from phosphoric acid production & is full of impurities

This material should be added to the National List as:

Synthetic Allowed Prohibited Natural

or, Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or, this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

mined product allowed

Please comment on the accuracy of the information in the file:

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? Yes; No

Signature Walter Jeffery Date 7/27/96

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
very little
- (4) the effect of the substance on human health;
non-toxic,
- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- (6) the alternatives to using the substance in terms of practices or other available materials; and
- (7) its compatibility with a system of sustainable agriculture.

NOSB Materials Database

1

Identification

Common Name **Calcium Sulfate** Chemical Name
Other Names
Code #: CAS Reg. No. 7778-18-9 Code #: Other
N. L. Category MSDS yes no

Chemistry

Family
Composition $\text{CaSO}_{4 \cdot x}\text{H}_2\text{O}$
Properties Calcium sulfate is anhydrous or contains two molecules of water of hydration. It occurs as a fine, white to slightly yellow white, odorless powder.
How Made

Use/Action

Type of Use Processing
Specific Use(s) Nutrient; dietary supplement; yeast food; dough conditioner; firming agent; sequestrant.
Action
Combinations

Status

OFPA
N. L. Restriction
EPA, FDA, etc
Directions
Safety Guidelines
Historical status
International status

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CALCIUM SULFATE, DIHYDRATE, POWDER
FORMULA: CASO4 2H2O
FORMULA WT:172.17
CAS NO.: 10101-41-4
NIOSH/RTECS NO.: EW4150000
COMMON SYNONYMS: GYPSUM; ALABASTER; C.I. 77231; C.I. PIGMENT WHITE 25
PRODUCT CODES: 1452
EFFECTIVE: 05/05/86
REVISION #01
PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 0 NONE
FLAMMABILITY - 0 NONE
REACTIVITY - 0 NONE
CONTACT - 1 SLIGHT
HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).
LABORATORY PROTECTIVE EQUIPMENT
SAFETY GLASSES; LAB COAT
PRECAUTIONARY LABEL STATEMENTS
CAUTION
MAY CAUSE IRRITATION
DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER
HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

2 - HAZARDOUS COMPONENTS

COMPONENT% CAS NO.
NOT APPLICABLE

3 - PHYSICAL DATA

BOILING POINT: N/AVAPOR PRESSURE(MM HG): N/A
MELTING POINT: N/AVAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 2.32 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)

SOLUBILITY(H2O): MODERATE (1 TO 10 %) % VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE, ODORLESS POWDER.

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP): N/A
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
USE EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE.

SPECIAL FIRE-FIGHTING PROCEDURES

FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.
TOXIC GASES PRODUCED

SULFUR DIOXIDE

5 - HEALTH HAZARD DATA

CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO

EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE EYES.

TARGET ORGANS

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CALCIUM SULFATE, 1/2-HYDRATE, POWDER

FORMULA: CASO4 1/2H2O

FORMULA WT:145.15

CAS NO.: 7778-18-9

COMMON SYNONYMS: PLASTER OF PARIS; DRIED GYPSUM

PRODUCT CODES: 1463

EFFECTIVE: 05/22/86

REVISION #01

PRECAUTIONARY LABELLING

BAKER SAF-T-DATA(TM) SYSTEM

HEALTH - 1 SLIGHT

FLAMMABILITY - 0 NONE

REACTIVITY - 0 NONE

CONTACT - 1 SLIGHT

HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).

LABORATORY PROTECTIVE EQUIPMENT

SAFETY GLASSES; LAB COAT

PRECAUTIONARY LABEL STATEMENTS

CAUTION

MAY CAUSE IRRITATION

DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

2 - HAZARDOUS COMPONENTS

COMPONENT% CAS NO.

NOT APPLICABLE

3 - PHYSICAL DATA

BOILING POINT: N/AVAPOR PRESSURE(MM HG): N/A

MELTING POINT: N/AVAPOR DENSITY(AIR=1): N/A

SPECIFIC GRAVITY: N/AEVAPORATION RATE: N/A

(H2O=1) (BUTYL ACETATE=1)

SOLUBILITY(H2O): SLIGHT (0.1 TO 1 %) % VOLATILES BY VOLUME: 0

MSDS for CALCIUM SULFATE, 1/2-HYDRATE, POWDER Page 2

APPEARANCE & ODOR: WHITE, ODORLESS POWDER.

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP: N/A

FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %

FIRE EXTINGUISHING MEDIA

USE EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE.

SPECIAL FIRE-FIGHTING PROCEDURES

FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.
TOXIC GASES PRODUCED
SULFUR DIOXIDE

5 - HEALTH HAZARD DATA

CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO
EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE SKIN OR EYES.

TARGET ORGANS

NONE IDENTIFIED

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE

NONE IDENTIFIED

ROUTES OF ENTRY

NONE INDICATED

EMERGENCY AND FIRST AID PROCEDURES

INGESTION: IF SWALLOWED AND THE PERSON IS CONSCIOUS, IMMEDIATELY GIVE LARGE AMOUNTS OF WATER. GET MEDICAL ATTENTION.

INHALATION: IF A PERSON BREATHES IN LARGE AMOUNTS, MOVE THE EXPOSED PERSON TO FRESH AIR. GET MEDICAL ATTENTION.

EYE CONTACT: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION.

SKIN CONTACT: IMMEDIATELY WASH WITH PLENTY OF SOAP AND WATER FOR AT LEAST 15 MINUTES.

6 - REACTIVITY DATA

STABILITY: STABLEHAZARDOUS POLYMERIZATION: WILL NOT OCCUR
CONDITIONS TO AVOID: NONE DOCUMENTED

MSDS for CALCIUM SULFATE, 1/2-HYDRATE, POWDER Page 3

INCOMPATIBLES: ALUMINUM, STRONG ACIDS

DECOMPOSITION PRODUCTS: OXIDES OF SULFUR

7 - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE

WEAR SUITABLE PROTECTIVE CLOTHING. CAREFULLY SWEEP UP AND REMOVE.

DISPOSAL PROCEDURE

DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL ENVIRONMENTAL REGULATIONS.

8 - PROTECTIVE EQUIPMENT

VENTILATION: USE ADEQUATE GENERAL OR LOCAL EXHAUST VENTILATION TO KEEP FUME OR DUST LEVELS AS LOW AS POSSIBLE.

RESPIRATORY PROTECTION: NONE REQUIRED WHERE ADEQUATE VENTILATION CONDITIONS EXIST. IF AIRBORNE CONCENTRATION IS

HIGH, USE AN APPROPRIATE RESPIRATOR OR DUST MASK.

EYE/SKIN PROTECTION: SAFETY GLASSES WITH SIDESHIELDS, PROPER GLOVES ARE RECOMMENDED.

9 - STORAGE AND HANDLING PRECAUTIONS

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

SPECIAL PRECAUTIONS

KEEP CONTAINER TIGHTLY CLOSED. SUITABLE FOR ANY GENERAL CHEMICAL STORAGE AREA.

10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

DOMESTIC (D.O.T.)

PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

INTERNATIONAL (I.M.O.)

PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

.

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CALCIUM SULFATE, ANHYDROUS, POWDER
FORMULA: CASO4
FORMULA WT:136.14
CAS NO.: 07778-18-9
COMMON SYNONYMS: ANHYDRITE; ANHYDROUS GYPSUM
PRODUCT CODES: 1458
EFFECTIVE: 05/22/86
REVISION #01
PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 1 SLIGHT
FLAMMABILITY - 0 NONE
REACTIVITY - 0 NONE
CONTACT - 1 SLIGHT
HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).
LABORATORY PROTECTIVE EQUIPMENT
SAFETY GLASSES; LAB COAT
PRECAUTIONARY LABEL STATEMENTS
CAUTION
MAY CAUSE IRRITATION
DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER
HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

2 - HAZARDOUS COMPONENTS

COMPONENT% CAS NO.
NOT APPLICABLE

3 - PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE(MM HG): N/A
MELTING POINT: 1450 C (2642 F) VAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 2.96 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): SLIGHT (0.1 TO 1 %) % VOLATILES BY VOLUME: 0

APPEARANCE & ODOR: WHITE ODORLESS GRANULES.

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP: N/A
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
USE EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE.
SPECIAL FIRE-FIGHTING PROCEDURES

