

now

allowed

# NOSB NATIONAL LIST FILE CHECKLIST

## PROCESSING

MATERIAL NAME: **Magnesium sulfate**

CATEGORY: Non-agricultural

Complete?: 3/17

✓

NOSB Database Form

✓

References

✓

MSDS (or equivalent)

✓

FASP (FDA)

✓

Date file mailed out: 2/14/95

✓

TAP Reviews from: Bob Durst

Steve Taylor

Richard Thayer

Supplemental Information:

MISSING INFORMATION: \_\_\_\_\_

# NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

Name of Material Magnesium sulfate

Type of Use:  Crops;  Livestock;  Processing

TAP Review by:

1. Steve Taylor
2. Richard Theuer
3. Bob Durst

Comments/Questions:

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My Opinion/Vote is:

Signature \_\_\_\_\_ Date \_\_\_\_\_

# USDA/TAP REVIEWER COMMENT FORM

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. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Feb '94

Name of Material: Mame Siam sulfate

Reviewer Name: Stwe Taylor

Is this substance Natural or Synthetic? Explain (if appropriate)

*Natural*

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

This material should be added to the National List as:

Synthetic Allowed       Prohibited Natural

or,  This material does not belong on the National List because:

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

Any additional comments or references?

Signature Stwe Taylor

Date 3-10-95



USDA/TAP REVIEWER  
COMMENT FORM

Original mailing date: 14 Feb 1995.

Name of Material: Magnesium Sulfate (epsom salt) 21CFR184.1443  
Reviewer Name: Richard C. Theuer

**NATURAL** Magnesium sulfate occurs naturally as the mineral epsomite. Some magnesium sulfate is recovered from waste brines from the potash industry, seawater bitterns, and natural brines. Magnesium sulfate recovered from seawater bitterns may be called "nigari."

**SYNTHETIC** Magnesium sulfate is produced synthetically by dissolving magnesium oxide, hydroxide or carbonate in sulfuric acid (synthetic) solution and evaporating it to crystallization.

**COMMENTS RE SECTION 2119(m) CRITERIA:**

1. Magnesium sulfate apparently is essential for tofu production.
2. Nigari has been used in Japan historically for tofu production. It is made from the brine left after salt is crystallized from seawater, so it is compatible with a sustainable system.
3. Magnesium sulfate is Generally Recognized As Safe.
4. Natural magnesium sulfate is available so the synthetic material should not be on the National List of Allowed Synthetics.

The following natural substance should be allowed as an ingredient in organic foods. It should not be added to the National List of natural substances prohibited for use as ingredients or processing aids in Organic Food:

magnesium sulfate  
(produced by mining epsomite or from brine).

February 22, 1995



# USDA/TAP Reviewer Comment Form

Material: Magnesium sulfate

Reviewer: Bob Durst

Is this substance Natural or Synthetic? Explain (if appropriate)

This is a synthetic material. It is necessary as a dietary supplement (nutrient).

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

The file is accurate.

This material should be added to the National List as:

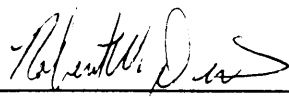
- Synthetic Allowed,
- Prohibited Natural, or
- This material does not belong on the National List because:

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

Should only be used as a nutrient (not as a processing aid), and must be listed on the ingredient label.

Any additional comments or references?

As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.

Signature 

Date 3/11/95





# NOSB Materials Database

4.

## Identification

Common Name **Magnesium sulfate** Chemical Name  
Other Names Epsom salt  
Code #: CAS Code #: Other  
N. L. Category Non-agricultural MSDS  yes  no

## Chemistry

### Family

Composition  $MgSO_4 \cdot 7H_2O$

Properties Small colorless crystals, usually needle-like, with a cooling, saline, bitter taste. Freely soluble in water, slowly soluble in glycerin, and sparingly soluble in alcohol. Solutions are neutral.

How Made Exists naturally as mineral: epsomite ( $MgSO_4 \cdot 7H_2O$ ) or kieserite ( $MgSO_4 \cdot H_2O$ ). Some magnesium sulfate is recovered from waste brines from the potash industry, seawater bitters, and natural brines. ~~Magnesium sulfate recovered from seawater bitters may be called "nigan".~~  
Magnesium sulfate is also produced synthetically by dissolving magnesium oxide, hydroxide or carbonate in sulfuric acid (synthetic) solution and evaporating it to crystallization.

Processing

## Use/Action

### Type of Use

Specific Use(s) Nutrient; dietary supplement. Essential for tofu production.

### Action

### Combinations

## Status

OFPA

N. L. Restriction

EPA, FDA, etc FDA-GRAS

Directions

Safety Guidelines

State Differences

Historical status

International status

## OFPA Criteria

2119(m)1: chemical interactions      Not Applicable

2119(m)2: toxicity & persistence      Not Applicable

2119(m)3: manufacture & disposal consequences

Low environmental impact from the brine produced material.

2119(m)4: effect on human health

No harmful effects at levels used in foods.

2119(m)5: agroecosystem biology      Not Applicable

2119(m)6: alternatives to substance

None for tofu production.

2119(m)7: Is it compatible?

## References

AU: Del-Valle,-F.R.; De-Alba,-E.; Mariscal,-G.; Jimenez,-P.G.; Arellanes,-J.A.; Portillo,-A.; Casas,-R.; Tristan,-M.E.; Dominguez,-G.M.

TI: Simultaneous curdling of soy/cow's milk blends with rennet and calcium or magnesium sulfate, utilizing soymilk prepared from soybeans or full-fat soy flour.

SO: J-Food-Sci. Chicago, Ill. : Institute of Food Technologists. July/Aug 1984. v. 49 (4) p. 1046-1052.

CN: DNAL 389.8-F7322

AU: Holgate,-A.M.; Read,-N.W.

TI: Relationship between small bowel transit time and absorption of a solid meal: Influence of metoclopramide, magnesium sulfate, and lactulose.

SO: Dig-Dis-Sci. New York : Plenum Publishing Corporation. Sept 1983. v. 28 (9) p. 812-819. ill., charts.

CN: 448.8-AM324

AB: Extract: The times taken for a radiolabeled solid meal to empty from the stomach and terminal ileum and the absorption of the components of that meal were measured in 14 patients with terminal ileostomies under control conditions and after administration of either lactulose (40 g) or metoclopramide (20 mg tds), or magnesium sulfate (0.1 g/kg body weight). All 3 agents significantly reduced the time taken for the meal to empty from the ileum. This was associated with significant reductions in the absorption of fat, carbohydrate, protein, water, and electrolytes in the case of lactulose and magnesium sulfate. It was therefore concluded that, although agents that accelerate postprandial transit of a meal may diminish absorption of the components of that meal in the small bowel, the extent to which this occurs cannot be predicted by a knowledge of transit kinetics alone and depends on the means by which transit is altered.

# MATERIAL SAFETY DATA SHEET

## MAGNESIUM SULFATE

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### SECTION I - Product Identification

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PRODUCT NAME: MAGNESIUM SULFATE  
FORMULA: MgSO4.7H2O  
FORMULA WT: 246.5  
CAS NO.:  
COMMON SYNONYMS: EPSOM SALT

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### Precautionary Labeling

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N/A

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### SECTION II - Hazardous Components

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N/A

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### SECTION III - Physical Data

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BOILING POINT: N/A                      VAPOR PRESSURE @ 20C (MM HG): N/A  
MELTING POINT: 75C                      VAPOR DENSITY (AIR=1): N/A  
SPECIFIC GRAVITY: 1.67                      EVAPORATION RATE: N/A  
(H2O=1)                                      (BUTYL ACETATE=1)  
SOLUBILITY(H2O): SOLUBLE                      PERCENT VOLATILES BY VOLUME: N/A  
APPEARANCE & ODOR: EFFORESENT CRYSTALS

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### SECTION IV - Fire and Explosion Hazard Data

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FLASH POINT: NONFLAMMABLE  
FLAMMABLE LIMITS: UPPER - N/A %    LOWER - N/A %  
FIRE EXTINGUISHING MEDIA  
  ANY SUITABLE FOR SURROUNDING MATERIALS  
SPECIAL FIRE-FIGHTING PROCEDURES  
  WEAR SELF-CONTAINED BREATHING APPARATUS  
UNUSUAL FIRE AND EXPLOSION HAZARDS  
  MAY EMIT TOXIC FUMES ON THERMAL DECOMPOSITION

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### SECTION V - Health Hazard Data

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THRESHOLD LIMIT VALUE (TLV/TWA): NONE ESTABLISHED  
TOXICITY: ORL-RBT LDLO: 3 G/KG  
EFFECTS OF OVEREXPOSURE  
  CAN CAUSE EYE AND SKIN IRRITATION. DUST INHALATION MAY IRRITATE  
  UPPER RESPIRATORY PASSAGES. MAGNESIUM INTOXICATION.  
EMERGENCY AND FIRST AID PROCEDURES  
  SKIN: WASH WITH SOAP/WATER, GET MEDICAL ASSISTANCE.  
  EYES: WASH WITH WATER, GET MEDICAL ASSISTANCE.  
  INHALATION: REMOVE TO FRESH AIR, GET MEDICAL ASSISTANCE.  
  INGESTION: GET MEDICAL ATTENTION.  
  GET MEDICAL ASSISTANCE FOR ALL CASES OF OVEREXPOSURE

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### SECTION VI - Reactivity Data

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STABILITY: STABLE  
CONDITIONS TO AVOID:  
INCOMPATIBLES: N/A  
DECOMPOSITION PRODUCTS: SOX

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**SECTION VII - Spill and Disposal Procedures**

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STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE  
SWEEP UP AND CONTAINERIZE

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**SECTION VIII - Protective Equipment**

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PROVIDE ADEQUATE GENERAL VENTILATION.  
PROTECT EYES AND SKIN WITH SAFETY GOGGLES AND GLOVES.

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**SECTION IX - Storage and Handling Precautions**

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STORE IN COOL, DRY, AREA.

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**SECTION X - Transportation Data and Additional Information**

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MELTING POINT: BEGINS TO LOSE WATER AT 75C

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(TM) and (R) : Registered Trademarks  
N/A = Not Applicable OR Not Available  
The information published in this Material Safety Data Sheet has been compiled from our experience and data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for adoption of necessary safety precautions. We reserve the right to revise Material Safety Data Sheets periodically as new information becomes available.  
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U. S. FOOD AND DRUG ADMINISTRATION  
FOOD ADDITIVE SAFETY PROFILE

MAGNESIUM SULFATE

AS#:	010034998	HUMAN CONSUMPTION:	0.7372	MG/KG BW/DAY/PERSON
SP#:	2340	MARKET DISAPPEARANCE:	870000.000	LBS/YR
PE:	ASP	MARKET SURVEY:	87	
AS#:	0117	JECFA:		
MA#:		JECFA ADI:		MG/KG BW/DAY/PERSON
AS#:		JECFA ESTABLISHED:	930915	
		LAST UPDATE:		

DENSITY: 120.37 LOGP:

STRUCTURE CATEGORIES: A7

COMPONENTS:

NONYMS:

EPSOM SALT  
MAGNESIUM SULFATE HEPTAHYDRATE  
SULFURIC ACID MAGNESIUM SALT (1:1), HEPTAHYDRATE  
MAGNESIUM SULFATE (1:1), HEPTAHYDRATE  
MAGNESIUM SULFATE HEPTAHYDRATE (MGSO4.7H2O)  
SULFATE, MAGNESIUM

CHEMICAL FUNCTION: G

TECHNICAL EFFECT:

MALTING OR FERMENTING AID  
NUTRIENT SUPPLEMENT  
FORMULATION AID  
PROCESSING AID  
PH CONTROL AGENT  
ANTICAKING AGENT OR FREE-FLOW AGENT  
EMULSIFIER OR EMULSIFIER SALT  
LUBRICANT OR RELEASE AGENT  
STABILIZER OR THICKENER

REG NUMBERS: 182.5443 184.1443

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1 FROM SCOGS-60

TOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

CNUM=2340

1                    COMPLETENESS:       SOURCE: ARCH PATHOL 73:400-403  
 SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1962  
 PE:                    RABBIT  
 ECIES:                LEL: >  
                       MG/KG BW/DAY  
 RATION: 90 DAYS       HNEL: 180       MG/KG BW/DAY  
 FECS: NO EFFECTS  
 TES:  
 MMENTS: DATA INSUFFICIENT FOR PRIORITY RANKING

X 3:       GENETIC TOXICITY STUDIES

2                    COMPLETENESS:       SOURCE:  
 PE:                    YEAR:  
 ECIES:                LEL:  
 RATION:               HNEL:       MG/KG BW/DAY  
 FECS:  
 LLS:  
 MMENTS: