NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **#14 Magnesium Stearate**

✓	**NOSB Database Form**
✓	**References**
____	**MSDS (or equivalent)**
✓	**FASP (FDA)**
✓	**TAP Reviews from:** **Joe Montecalvo, Rich Theuer**

NOSB/NATIONAL LIST
COMMENT FORM
PROCESSING

Material Name: #14 Magnesium Stearate

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

COMMENTS/QUESTIONS:

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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: Sept. 5, 1995

Name of Material: Magnesium Stearate

Reviewer Name: R THEUER

Is this substance Synthetic or non-synthetic? Explain (if appropriate) SYNTHETIC - MAGNESIUM SALT OF "STEARIC ACID"

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

STEARIC ACID IS PRODUCED BY SAPONIFICATION OF FAT (OLD WAY TO MAKE SOAP [LYE + TALLOW], FOLLOWED BY ACID TO GET STEARIC ACID. MAGNESIUM ADDED (AS PROBABLY HYDROXIDE) TO FORM MAGNESIUM STEARATE

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?

USED IN SMALL AMOUNTS AS A LUBRICANT, ANTI-CAKING AGENT IN SALT. MAY BE AN "INCIDENTAL" ADDITIVE AT TIMES

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

NOT ENOUGH ON MANUFACTURE PROCESS

Any additional comments? (attachments welcomed)

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

Signature Richard C Theuer **Date** 8/28/95

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- MAGNESIUM IS IN SOIL
FATTY ACID ARE BIODEGRADABLE

(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 AT NORMAL INTAKE & USAGE LEVELS

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

DISPOSAL OF SPENT LYE LIQUOR FROM SOAP MANUFACTURE CAN CREATE A PROBLEM. USAGE HERE IS VERY SMALL, THOUGH.

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

NORMAL NUTRIENTS - OK

(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;

OK

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

TALC FOR LUBRICATION, BUT SOME CONCERN ABOUT ASBESTOS

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

OK

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: Sept 5, 1995

Name of Material: Magnesium Stearate

Reviewer Name: DR. JOE MONTECALVO

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) Mg. salt of stearic acid, Octadecanoic Acid, it is a saturated fatty acid. Can be extracted as a glyceride from beef tallow and other animal fats, can be prepared synthetically by hydrogenation of cottonseed and/or other vegetable oils.

This material should be added to the National List as:

__L__ **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?

- Recommended only for nutritional supplements, binding agents and anticaking agent.
- There are other processing aids for its additional usages.

Please comment on the accuracy of the information in the file: - O.K

Any additional comments? (attachments welcomed)

Major uses - in Baby powder dusting powders - Food use - As a tablet lubricant

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

Signature [signature] **Date** 8/22/95

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;**

As with all saturated fatty acids in the diet, it may have a negative effect on serum cholesterol levels.

(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** -see front page.

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

Only for specific applications

Identification

Common Name **Magnesium stearate** **Chemical Name**

Other Names

Code #: CAS **Code #: Other**

N. L. Category Synthetic Allowed **MSDS** ○ yes ○ no

Chemistry

Family

Composition $C_{36}H_{70}MgO_4$

Properties A compound of magnesium with a mixture of solid organic acids obtained from edible sources. A fine white bulky powder having a faint, characteristic odor. Insoluble in water, in alcohol and in ether.

How Made

Use/Action

Type of Use Processing

Specific Use(s) Formulation iad, Lubricant; anticaking agent; binder; emulsifier. In nutritional supplements.

Action

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc

Directions

Safety Guidelines

State Differences

Historical status

Internationl status

OFPA Criteria

2119(m)1: chemical interactions Not Applicable

2119(m)2: toxicity & persistence Not Applicable

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

2119(m)5: agroecosystem biology Not Applicable

2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

References

The Merck Index, 10th edition. 1983. Merck and Co., Inc., Rahway, NJ

CNUM=2339

U.S. FOOD AND DRUG ADMINISTRATION
FOOD ADDITIVE SAFETY PROFILE

MAGNESIUM STEARATE

.S#:	000557040	HUMAN CONSUMPTION:	0.2019	MG/KG BW/DAY/PERSON
.SP#:	2339	MARKET DISAPPEARANCE:	238333.333	LBS/YR
PE:	ASP	MARKET SURVEY:	87	
.S#:	0116	JECFA:	NO-C	
MA#:		JECFA ADI:		MG/KG BW/DAY/PERSON
AS#:		JECFA ESTABLISHED:	1985	
		LAST UPDATE:	930115	
:	591.2	DENSITY:	LOGP:	

RUCTURE CATEGORIES: A3

MPONENTS:

NONYMS: OCTADECANOIC ACID, MAGNESIUM SALT
MAGNESIUM OCTADECANOATE
STEARIC ACID, MAGNESIUM SALT

EMICAL FUNCTION: D

CHNICAL EFFECT: FORMULATION AID
ANTICAKING AGENT OR FREE-FLOW AGENT
DRYING AGENT
HUMECTANT

R REG NUMBERS: 173.340 184.1440 172.863
175.300

NIMUM TESTING LEVEL: 3

MMENTS: NO TOX STUDIES FROM SCOGS-60

X 4A: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE RAT OR MOUSE STUDIES

UDY: 4 COMPLETENESS: A RANKING FACTOR: 8.076E-5
ECIES: RAT LEL: 2500 MG/KG BW/DAY
FECTS: ORGAN WEIGHT DECREASE
TES: KIDNEY
MMENTS: DECREASED RELATIVE KIDNEY WEIGHT IN FEMALES

CNUM=2339

X 4C: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES

UDY: 4 COMPLETENESS: A RANKING FACTOR: 0.000E0
ECIES: RAT LEL: 2500 MG/KG BW/DAY
FECTS: ORGAN WEIGHT DECREASE
TES: KIDNEY
MMENTS: DECREASED RELATIVE KIDNEY WEIGHT IN FEMALES

X 7: ACUTE TOXICITY INFORMATION

UDY: 2 SOURCE: CMF 000009 43:11422
ECIES: RAT YEAR: 1970
LD50: 5000 MG/KG BW
MMENTS: STUDY 2 LD50 => 5000 MG/KG; MALES ONLY

X 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

UDY: 4 COMPLETENESS: A SOURCE: TOXICOLOGY 17:51-55
PE: SUBCHRONIC RODENT YEAR: 1980
ECIES: RAT LEL: 2500 MG/KG BW/DAY
RATION: 90 DAYS HNEL:
FECTS: ORGAN WEIGHT DECREASE
TES: KIDNEY
MMENTS: RELATIVE KIDNEY WT DECREASE FOR FEMALES
DECREASED PCV AT 10000 MG/KG
DECREASED RELATIVE LIVER WEIGHT AT 10000 MG/KG FOR MALES
4/20 MALES DIED AT 10000 MG/KG
INCREASED STONE FORMATION IN URINARY TRACT AT 10000 MG/KG IN MALES

X 3: GENETIC TOXICITY STUDIES

UDY: 3 COMPLETENESS: SOURCE:
PE: YEAR:
ECIES: LEL: MG/KG BW/DAY
RATION: HNEL:
FECTS:
LLS:
MMENTS:
