NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **#4 Calcium Citrate**

✓ **NOSB Database Form**

✓ **References**

____ **MSDS (or equivalent)**

____ **FASP (FDA)**

✓ **TAP Reviews from:** **Joe Montecalvo, Rich Theuer**

NOSB/NATIONAL LIST
COMMENT FORM
PROCESSING

Material Name: #4 Calcium Citrate

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: Calcium Citrate

Reviewer Name: R THEUER

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)

SEE MY SHEET DATED 12 MAR 95

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?

NO - LIMITED NOW BY GMP'S

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

O/K

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

(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;

VERY LOW

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

ESSENTIAL METABOLITE = CITRATE

ESSENTIAL MINERAL = 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;

NONE - BIODEGRADABLE

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

SOMETIMES OTHER CALCIUM SALTS CAN REPLACE CALCIUM CITRATE. CALCIUM CITRATE HAS GOOD BIOAVAILABILITY

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

GOOD

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date: 14 Feb 1995.

Name of Material:	Calcium Citrate	21CFR182.1195
		21CFR182.5195
		21CFR182.6195
	Potassium Citrate	21CFR182.1625
		21CFR182.6625
	Sodium Citrate	21CFR182.1751
		21CFR182.6751
Reviewer Name:	Richard C. Theuer	

SYNTHETIC Citric acid salts of calcium, potassium and sodium are prepared by the neutralization of purified citric acid with a suitable pH adjusting agent (calcium hydroxide, potassium hydroxide or sodium hydroxide, respectively). These pH adjusting agents are synthetic so the resulting citrate salts are equally synthetic. Citric acid is normally produced by fermentation of a glucose or other carbohydrate substrate by citric acid bacteria so it is natural, in the judgment of this reviewer, even though citric acid is reacted with calcium to form the insoluble calcium citrate in a step integral to its isolation and purification.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Citric acid is an essential cell metabolite. The "citric acid cycle" is a critical metabolic pathway in animals. Calcium, potassium and sodium are all essential nutrients for man and other animals.
2. These citrate salts are multipurpose GRAS food ingredients. They are used as nutrients, sequestrants (chelating agents), pH adjusting agents, buffering agents, etc.
4. Alternatives to the citrates in some applications are various phosphates. Similar pH control and sequestrant action can be achieved with sodium citrate and sodium phosphate, but sodium citrate will not alter the phosphate level in the food.

The following substances should be added to the National List of Substances as allowed synthetic ingredients in Organic Food:

calcium citrate
potassium citrates
sodium citrates.

12 Mar 1995

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: Calcium Citrate

Reviewer Name: Dr. Joe Montecalvo

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

Synthetic Allowed

If synthetic, how is the material made? (please answer here if our database form is blank) – may be produced by microlological fermentation on an industrial scale using crude sugar solutions such as molasses and strains of Aspergillus niger. Also may be extracted from citrus fruits (lemon 5-8%) and pinapple waste.

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?

NO

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

Any additional comments? (attachments welcomed)

this is the Calcium form of Citric Acid (ie. Citric Acid salt)

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

Signature [signature] **Date** 8/27/95

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; it can donate Calcium ions and Reduce pH of soil.

(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; NO DATA Available.

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

minimal

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

No data/studies Available

(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; to the best of my Knowledge.

(6) the alternatives to using the substance in terms of practices or other available materials; and Few, if any, Alternatives with the same Functionality.

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

O.K here

NOSB Materials Database

Identification

Common Name	**Calcium citrate**	Chemical Name	
Other Names			
Code #: CAS		Code #: Other	
N. L. Category	Synthetic Allowed	MSDS	O yes O no

Chemistry

Family	
Composition	$Ca_3(C_6H_5O_7)_2.4H_2O$
Properties	A fine white odorless powder. Very slightly soluble in water and insoluble in alcohol.
How Made	prepared from citrus fruits.

Use/Action

Type of Use	Processing
Specific Use(s)	Sequestrant, buffer, firming agent, calcium source. Used in production of citric acid. Improves baking properties of flour.
Action	
Combinations	

Status

OFPA	
N. L. Restriction	
EPA, FDA, etc	FDA-GRAS
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

also See attached.

CALCIUM CITRATE REFERENCES

AU: Garcia-Lopez,-S.; Miller,-G.D.
TI: Bioavailability of calcium from four different sources.
SO: Nutr-Res. Tarrytown, N.Y. : Pergamon Press. Oct 1991. v. 11 (10) p. 1187-1196.
CN: DNAL QP141.A1N88
AB: Bone mineralization and mineral retention were measured to evaluate calcium (Ca) bioavailability from four different sources at two dietary levels (40% or 100% of NRC requirement). The bioavailability of Ca from Ca carbonate, Ca citrate, tricalcium phosphate, and reduced particle size Ca citrate was determined in Sprague Dawley rats. There was no significant effect of Ca source on percent Ca retained or femur Ca concentrations at either level of Ca tested. Animals fed the 0.2% Ca diets retained a larger percent of ingested Ca and had lower bone calcium levels than those fed 0.5% Ca Diets. These results indicate that, in the rat, there is no significant difference in Ca bioavailability from the four sources tested.

AU: Buchowski,-M.S.; Miller,-D.D.
TI: Lactose, calcium source and age affect calcium bioavailability in rats.
SO: J-Nutr. Bethesda, Md. : American Institute of Nutrition. Nov 1991. v. 121 (11) p. 1746-1754.
CN: DNAL 389.8-J82
AB: Calcium bioavailability was defined as either retention of 45Ca in tibias (Experiment 1) or retention of 47Ca in carcasses (Experiment 2). In Experiment 1, rats (age 21, 40 or 100 d) were fed purified meals extrinsically labeled with 45Ca. The meals contained either 0.5% Ca (control) or 1% Ca [control supplemented with CaCO3, calcium citrate-malate (CCM), milk or cheese] and either no lactose or 20% lactose. Lactose increased Ca bioavailability ($P < 0.05$) from the control and milk meals in all age groups. Increases from CCM arid CaCO3 were significantly only in the 21-d-old group. In Experiment 2, suckling rats (age 7, 12 or 17 d) were gavaged with 47Ca-labeled milk (fluid skim or lactose-hydrolyzed fluid skim) or an aqueous CaCl2-casein mixture (containing either no sugar, glucose + galactose, or lactose). Bioavailability from milk was higher than from lactose-hydrolyzed milk in all age groups. Data from these experiments show that lactose enhances Ca bioavailability at several stages of development and the effect is not markedly diminished by high Ca diets. Lactose increases Ca bioavailability from a variety of sources but the magnitude of the effect may vary among sources.

AU: Harvey,-J.A.; Kenny,-P.; Poindexter,-J.; Pak,-C.Y.C.
TI: Superior calcium absorption from calcium citrate than calcium carbonate using external forearm counting.
SO: J-Am-Coll-Nutr. New York, N.Y. : John Wiley & Sons. Dec 1990. v. 9 (6) p. 583-587. charts.
CN: DNAL RC620.A1J6
AB: Calcium absorption from calcium citrate was compared with that obtained from calcium carbonate in 20 normal women. It was measured by external forearm counting technique, where the ratio of forearm radioactivity after an oral dose of labeled calcium salt (containing 500 mg calcium) and after an intravenous injection of trace radiocalcium represented fractional calcium absorption. The fractional calcium absorption from calcium citrate was 39.2 +/- 8.6%, which was significantly higher than the 31.2 +/- 9.4% derived from calcium carbonate ($p < 0.001$). Seventeen subjects displayed greater calcium absorption from calcium citrate. The remaining three patients, with a lower calcium absorption from the citrate salt, had high levels of calcium absorption from calcium carbonate. It is concluded that calcium is better absorbed from calcium citrate than calcium carbonate when these salts are taken on an empty stomach in most women. The exception might be those with optimum calcium absorption from calcium carbonate.

AU: Padival,-R-A; Bhatnagar,-H-C; Nair,-K-G; Narayana,-K
TI: Preparation of calcium citrate and sodium citrate from limes (Citrus aurantifolia)
SO: J-Food-Sci-Technol-Mysore, Sept 1971, 8 (3): 110-113. Ref.
CN: DNAL 389.8-J823