NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **#19 Potassium 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: #19 Potassium 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: Potassium Citrate

Reviewer Name: RC 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)

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?

LIMITED BY GMP'S, COST – NO RESTRICTION REQUIRED

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 RC 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

K is an essential nutrient for plants

(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;

O/C

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

VERY LIMITED -

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

POSITIVE

(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;

O/C

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

PHOSPHATES CAN REPLACE CITRATES. CITRATES CAUSE LESS ENVIRONMENTAL DAMAGE THAN PHOSPHATES DURING MANUFACTURE

(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: Potassium citrate

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)

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: O.K.

Any additional comments? (attachments welcomed)

Also used in Antacid formulations; the monobasic form is used as a 0.05 Molal solution as a standard for pH scale (pH$_{25°C}$ = 3.776

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

(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;

None

(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.

O.K.

NOSB Materials Database

Identification

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

Chemistry

Family	
Composition	$C_6H_5K_3O_7.H_2O$
Properties	Transparent crystals or a white granular powder. Odorless, has a cooling, saline taste, and is deliquescent when exposed to moist air. Almost insoluble in alcohol.
How Made	Made by treatment of citric acid with potassium hydroxide. Potassium hydroxide is made by electrolysis of potassium chloride, which is mined. KOH is not natural; citric acid is.

Use/Action

Type of Use	Processing
Specific Use(s)	pH control agent; buffer; sequestrant, nutrient.
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

No harmful effects at levels used in foods.

2119(m)5: agroecosystem biology **Not Applicable**

2119(m)6: alternatives to substance

various phosphates will substitute in some situations.

2119(m)7: Is it compatible?

References

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