Non 5
Syn 5

allowed

NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **Citric Acid**

CATEGORY: Synthetic Allowed

Complete?: 3/16

✓ **NOSB Database Form**

✓ **References**

✓ **MSDS** (or equivalent)

✓ **FASP (FDA)**

✓ **Date file mailed out:** 1/8/95

✓ **TAP Reviews from:** Steve Taylor
Steven Harper
Bob Durst

Supplemental Information:

Microbial form only ....
because of substrate might be
a product

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 Citric Acid

Type of Use: _____ **Crops;** _____ **Livestock;** ✓ **Processing**

TAP Review by:

1. Steve Taylor
2. Steven Harper
3. Bob Durst

Comments/Questions:

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: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steve 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?

Made by fermentation. Fermentation is natural but process does ~~any~~ involve use of other substances: substrates: corn syrup, sucrose ammonium bicarbonate

Any additional comments or references?

Need to find out more about process and processing aids to make determination.

Signature Steve Taylor **Date** 3-5-95

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: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steven Harper

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

Synthetic

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

Good

This material should be added to the National List as:

__x__ **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?

No.

Any additional comments or references?

Signature Steven Harper **Date** 3/10/95

USDA/TAP Reviewer Comment Form

Material: Citric acid

Reviewer: Bob Durst

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

It is a natural occurring substance that commercially goes through numerous chemical processes to get to it's final usable form. This processing would suggest that it be classified as synthetic.

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:

__X__ 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?

Must be listed on the ingredient label if it used used.

Unless it is actually derived from a natural source the labeling must not indicate that it is a natural compound.

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.

Since citrus juices are a high natural source of citric acid, it might be advisable to find a manufacturer that is willing to isolate citric acid from organically grown fruit in an organically acceptable manner, and get a natural citric acid.

Signature Robert W. Durst Date 3/4/95

NOSB Materials Database

Identification

Common Name	**Citric Acid**	**Chemical Name**	B-hydroxy-tricarboxylic acid C6H8O7
Other Names	Citric Acid, Anhydrous USP/FCC		
Code #: CAS	77-92-9	**Code #: Other**	21 CFR 182-1033
N. L. Category	Synthetic Allowed	**MSDS**	◉ yes ○ no

Chemistry

Family	Aliphatic Acid
Composition	$C_6H_8O_7$
Properties	Colorless, translucent crystals, (or) white granular to fine crystalline powder, odorless, strong acid taste.
How Made	Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid.

Use/Action

Type of Use	Processing
Specific Use(s)	Production of fruit products, juices, oils, fats etc. for pH control, flavor enhancer, flavoring agent or adjuvant, leavening agent, sequestrant, antioxidant, solvent, antimicrogial agent, surface-active agent.
Action	Optimizes stability of frozen foods by enhancing the action of antioxidants and inactivating enzymes. Brings out flavor in carbonated beverages. Acts as a synergist for antioxidants employed in inhibiting rancidity in foods containg fats and oils.
Combinations	pure substance

Status

OFPA	
N. L. Restriction	Currently considered synthetic by NOSB.
EPA, FDA, etc	FDA -GRAS
Directions	
Safety Guidelines	Eye irritant, dust may cause mild respiratory irritation.
State Differences	
Historical status	Always been allowed in organic processing and considered natural.
Internationl status	Allowed by IFOAM, EU and Codex.

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions **Not Applicable**

2119(m)2: toxicity & persistence **Not Applicable**

2119(m)3: manufacture & disposal consequences

Microbial fermentation --Clarification --Precipitation --Dissolution --Crystallization --Drying --Sifting --packaging. The NOSB judged that citric acid produced by natural fermentation of carbohydrate substrates and purified by the lime-sulfuric method is synthetic because the citric acid comes into contact with lime and sulfuric acid and because of the chemical change from citric acid to calcium citrate and then back to citric acid during purification.

Biomass residuals are usually recycled as animal feeds and for agriculture.

2119(m)4: effect on human health

Material has been affirmed as GRAS by FDA for use in foods. The amount of citrate added to foods by food processors is about 500 mg per person per day. This amount occurs naturally in 2 ounces of orange juice and does not constitute a significant addition to the total body load.

Long term oral over exposure may cause damage to tooth enamel. Considered an irritatant to eyes and respiratory system during manufacture and handling. Recommended use of eye and respiratory protection during handling. Oral LD50 (rat) 11,700 mg/kg; dermal (acute) tested on skin of rabbit 500mg/24 hr moderate; eye 750 mg/24hr severe. FDA tests show no effect on reproduction, teratogenicity or oncogenicity in rats.

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

2119(m)6: alternatives to substance

Lactic acid (has some taste problems and not used in infant foods).
Vinegar (strange taste in some foods).
Citrus juices.

2119(m)7: Is it compatible?

Compatible

References

1. FDA. 1977. Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. SCOGS-84. Life Science Research Office, 9650 Rockville Pike, Bethesda, Maryland 20014.

2. Ag Partners of Davis, *Materials Report for Citric Acid*, 1995. Organic Trade Association, Greenfield, MA

MSDS for CITRIC ACID, MONOHYDRATE

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CITRIC ACID, MONOHYDRATE
FORMULA: HOC(COOH)(CH2COOH)2 H2O FORMULA WT: 210.14
CAS NO.: 5949-29-1
COMMON SYNONYMS: 2-HYDROXY-1,2,3,PROPANE-TRICARBOXYLIC ACID, MONOHYDRATE
PRODUCT CODES: 0118,0120,0119,0110
EFFECTIVE: 12/01/86 REVISION #02

PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 0 NONE
FLAMMABILITY - 1 SLIGHT
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.
CITRIC ACID, MONOHYDRATE		05949-29-1

3 - PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE(MM HG): N/A
MELTING POINT: N/A VAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 1.54 (H2O=1) EVAPORATION RATE: N/A (BUTYL ACETATE=1)
SOLUBILITY(H2O): APPRECIABLE (MORE THAN 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 WATER SPRAY, CARBON DIOXIDE, DRY CHEMICAL OR ORDINARY FOAM.

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: CARBON MONOXIDE, CARBON DIOXIDE

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5 - HEALTH HAZARD DATA

TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT.

TOXICITY: LD50 (ORAL-RAT)(G/KG) - 11.7
LD50 (IPR-RAT)(MG/KG) - 883
LD50 (SCU-RAT)(MG/KG) - 5500
LD50 (ORAL-MOUSE)(MG/KG) - 5040

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

EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE NOSE AND THROAT.
DUST MAY CAUSE HEADACHE, COUGHING, DIZZINESS OR DIFFICULT BREATHING.
DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.
CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.

TARGET ORGANS: EYES, SKIN

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED

ROUTES OF ENTRY: INHALATION, EYE CONTACT, SKIN CONTACT

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.

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6 - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR

INCOMPATIBLES: STRONG BASES

DECOMPOSITION PRODUCTS: CARBON MONOXIDE, CARBON DIOXIDE

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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.

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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, NITRILE GLOVES 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)

DOCNUM=1937

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

CITRIC ACID

CAS#:	000077929	HUMAN CONSUMPTION:	90.5367	MG/KG BW/DAY/PERSON
FASP#:	1937	MARKET DISAPPEARANCE:	106833333.333LBS/YR	
TYPE:	ASP	MARKET SURVEY:	87	
NAS#:	2306	JECFA:	NL-C	
FEMA#:	2306	JECFA ADI:		MG/KG BW/DAY/PERSON
GRAS#:	3	JECFA ESTABLISHED:	1979	
POTENTIAL BEVERAGE USE		LAST UPDATE:	931115	
FW:	192.12	DENSITY:	LOGP:	

STRUCTURE CATEGORIES: A6

COMPONENTS:

SYNONYMS:
CITRIC ACID, ANHYDROUS
2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID
HYDROXYTRICARBOXYLIC ACID, BETA-
1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-
ACIDE CITRIQUE

CHEMICAL FUNCTION: F

TECHNICAL EFFECT:
PH CONTROL AGENT
FLAVOR ENHANCER
FLAVORING AGENT OR ADJUVANT
LEAVENING AGENT
SEQUESTRANT
ANTIOXIDANT
SOLVENT OR VEHICLE
SURFACE-ACTIVE AGENT
ANTIMICROBIAL AGENT
ENZYME

CFR REG NUMBERS:

173.165	172.755	182.6033
182.1033	PART 133	PART 146
161.190	PART 169	PART 150
155.130	145.145	131.111
131.112	131.136	131.144
131.138	131.146	146.187
150.161	150.141	166.40
169.115	169.140	169.150
173.160	173.280	145.131
166.110	184.1033	

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1-12 FROM SCOGS-84

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

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

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

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS
SPLEEN
COMMENTS: MALES ONLY
SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
DATA FROM SCOGS-84

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 2 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: RAT YEAR: 1971
LD50: 12000 MG/KG BW
COMMENTS:

STUDY: 1 SOURCE: J TAKEDA RES LAB 30:25-31
SPECIES: MOUSE YEAR: 1971
LD50: 5000 MG/KG BW
COMMENTS:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 3 COMPLETENESS: SOURCE: REV PORT FARM 20:41-46
TYPE: SHORT TERM YEAR: 1970
SPECIES: RAT LEL: 200 MG/KG BW/DAY
DURATION: 9 DAYS HNEL:
EFFECTS: BODY WEIGHT DECREASE
SITES:
COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST
NOT USED FOR PRIORITY RANKING

STUDY: 4 COMPLETENESS: SOURCE: J TAKEDA RES LAB 30:25-31
TYPE: SHORT TERM YEAR: 1971
SPECIES: RAT LEL: 4670 MG/KG BW/DAY
DURATION: 42 DAYS HNEL: 2260 MG/KG BW/DAY
EFFECTS: CHOLESTEROL DECREASE
GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
ORGAN WEIGHT DECREASE
CELLULAR ATROPHY
SITES: THYMUS SPLEEN
COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES

STUDY: 5 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED 34:86-89
TYPE: SUBCHRONIC RODENT YEAR: 1945
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 90 DAYS HNEL: 600 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: BODY WEIGHT, BLOOD, HISTOPATH AND REPRODUCTION OBSERVED

STUDY: 6 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED 34:86-89
TYPE: SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1945
SPECIES: DOG LEL: > MG/KG BW/DAY
DURATION: 112 DAYS HNEL: 1380 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: NO BEHAVIORAL, BIOCHEMICAL OR HISTOPATHOLOGICAL ABNORMALITIES

STUDY: 10 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RAT LEL: > MG/KG BW/DAY

DURATION: 10 DAYS HNEL: 295 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 9 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: MOUSE LEL: > MG/KG BW/DAY
DURATION: 10 DAYS HNEL: 241 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 11 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: HAMSTER LEL: > MG/KG BW/DAY
DURATION: 5 DAYS HNEL: 272 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-10 OF GESTATION

STUDY: 12 COMPLETENESS: SOURCE: GRP 7T0195 3
TYPE: TERATOGENICITY YEAR: 1973
SPECIES: RABBIT LEL: > MG/KG BW/DAY
DURATION: 13 DAYS HNEL: 425 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: ADMINISTERED DAY 6-18 OF GESTATION

STUDY: 8 COMPLETENESS: SOURCE: J AGRIC FOOD CHEM 5:759-760
TYPE: RAT ONCOGENICITY YEAR: 1957
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: 728 DAYS HNEL: 2000 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS: MALES ONLY

STUDY: 7 COMPLETENESS: SOURCE: VOEDING 17:137-148
TYPE: REPRODUCTION (3-GENERATION) YEAR: 1956
SPECIES: RAT LEL: > MG/KG BW/DAY
DURATION: HNEL: 800 MG/KG BW/DAY
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

BOX 3: GENETIC TOXICITY STUDIES

STUDY: 15 COMPLETENESS: SOURCE:
TYPE: YEAR:
SPECIES: LEL: MG/KG BW/DAY
DURATION: HNEL:
EFFECTS:
CELLS:
COMMENTS: