Syn allowed

NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: **Sodium citrates**

CATEGORY: Synthetic Allowed **Complete?:** 3/17

✓ **NOSB Database Form**

✓ **References**

✓ **MSDS** (or equivalent)

✓ **FASP (FDA)**

✓ **Date file mailed out:** 2/14/95

✓ **TAP Reviews from:** Bob Durst
Richard Theuer
Steven Harper

_____ **Supplemental Information:**

MISSING INFORMATION: _____

USDA/TAP Reviewer Comment Form

Material: Sodium citrates

Reviewer: Bob Durst

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

It is a synthetic substance.

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: see comments below.

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.

Any additional comments or references?

There are alternatives to the use of sodium citrate. These would include citric acid, and potassium citrate. Since there is a chance of producing an 'organic' citric acid, and the use of the potassium salt has some slight health benefit (in the reduction of sodium intake) it might be considered for exclusion from the list.

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

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

NOSB Materials Database

4.

Identification

Common Name **Sodium citrates**

Chemical Name 1,2,3 Propanetri-carboxylic acid

Other Names Trisodium Citrate

Code #: CAS 6132-04-3

Code #: Other

N. L. Category Synthetic Allowed

MSDS ◉ yes ○ no

Chemistry

Family

Composition $C_6H_5Na_3O_7.2H_2O$

Properties May be anhydrous or contain two molecules of water of crystallization. Colorless crystals or white crystalline powder. Soluble in water, insoluble in alcohol.

How Made Fermentation of carbohydrates to citric acid. Citric acid is reacted with sodium hydroxide.

Processing

Use/Action

Type of Use

Specific Use(s) pH control agent (buffer), flavor enhancer, stabilizer. Nutrient for cultured buttermilk. Soft drinks, cheese, ice cream, sauces.

Action Buffering action to prevent coagulation of proteins and other chemical components.

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

No, fully biodegradable.

2119(m)4: effect on human health

GRAS and is naturally occurring in milk.

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

2119(m)6: alternatives to substance

Phosphates, citric acid, potassium citrate.

2119(m)7: Is it compatible?

Non-toxic, occurs naturally, and is absolutely necessary for production in dairy systems. (SH).

References

Food Chemicals Codex, 3rd Ed., National Academy Press, Washington D.C. 1981.

Jean-Jacques Mathieu, Technical Services, ADM Food Additives Division, 1995, written communication.

MSDS for SODIUM CITRATE, DIHYDRATE

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: SODIUM CITRATE, DIHYDRATE
FORMULA: HOC(COONA)(CH2COONA)2 2H2O
FORMULA WT: 294.10
CAS NO.: 06132-04-3 NIOSH/RTECS NO.: GE8300000
COMMON SYNONYMS: TRISODIUM CITRATE PRODUCT CODES: 3646,3649,3650
EFFECTIVE: 11/25/86 REVISION #03

PRECAUTIONARY LABELLING
BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 0 NONE
FLAMMABILITY - 0 NONE
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.
NOT APPLICABLE		

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: N/A EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE ODORLESS CRYSTALS, GRANULES, OR 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 EXTINGUISHING MEDIA APPROPRIATE FOR SURROUNDING FIRE.
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

5 - HEALTH HAZARD DATA

TOXICITY: LD50 (IPR-RAT)(MG/KG) - 1548 LD50 (IV-MOUSE) (MG/KG) - 170
CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO
EFFECTS OF OVEREXPOSURE
CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.
INHALATION OF DUST MAY CAUSE IRRITATION TO UPPER RESPIRATORY TRACT.
TARGET ORGANS: NONE IDENTIFIED
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED
ROUTES OF ENTRY: INHALATION, SKIN CONTACT, EYE 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.

6 - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR
CONDITIONS TO AVOID: FLAME
DECOMPOSITION PRODUCTS: CARBON MONOXIDE, CARBON DIOXIDE

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.

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, GLOVES ARE 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 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)

)CNUM=2737

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

SODIUM CITRATE

,S#:	000068042	HUMAN CONSUMPTION:	22.3163	MG/KG BW/DAY/PERSON
,SP#:	2737	MARKET DISAPPEARANCE:	26333333.333	LBS/YR
'PE:	ASP	MARKET SURVEY:	87	
,S#:	3026	JECFA:	NL-C	
:MA#:	3026	JECFA ADI:		MG/KG BW/DAY/PERSON
:AS#:	3	JECFA ESTABLISHED:	1979	
)TENTIAL BEVERAGE USE		LAST UPDATE:	940115	
/:	258.07	DENSITY:	LOGP:	

'RUCTURE CATEGORIES: A6

)MPONENTS:

'NONYMS:
TRISODIUM CITRATE, ANHYDROUS
TRISODIUM CITRATE
1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT
TRISODIUM 2-HYDROXY-1,2,3-PROPANETRICARBOXYLATE
CITRIC ACID, TRISODIUM SALT
SODIUM CITRATE (NA3C6H5O7)
CITRATE, SODIUM
CITRATE, TRISODIUM

(EMICAL FUNCTION: F

:CHNICAL EFFECT:
EMULSIFIER OR EMULSIFIER SALT
PH CONTROL AGENT
COLOR OR COLORING ADJUNCT
SURFACE-ACTIVE AGENT
NUTRIENT SUPPLEMENT
SEQUESTRANT
FLAVORING AGENT OR ADJUVANT
STABILIZER OR THICKENER
MALTING OR FERMENTING AID

'R REG NUMBERS:

182.1751	182.6751	133.169
150.141	150.161	131.185
131.160	133.179	131.111
131.112	131.144	133.173
131.138	131.146	184.1751

:NIMUM TESTING LEVEL: 3

8

)CNUM=2737

)MMENTS: STUDY 1 FROM SCOGS-84

)X 7: ACUTE TOXICITY INFORMATION

'UDY: 10 SOURCE: ARCH INST PASTEUR D'ALGERIE XXX (1):55-56
'ECIES: RAT YEAR: 1952
LD50: 1240 MG/KG BW
)MMENTS: STYDY 10 LD50 => 1240 MG/KG

'UDY: 1 SOURCE: THEOR MED 19:625-630
'ECIES: MOUSE YEAR: 1965
LD50: 7100 MG/KG BW
)MMENTS: STUDY 9 => 1240 MG/KG

'UDY: 11 SOURCE: ARCH INST PASTEUR D'ALGERIE XXX (1):55-56
'ECIES: GUINEA PIG YEAR: 1952
LD50: 1240 MG/KG BW
)MMENTS: STUDY 11 LD50 => 1240 MG/KG

)X 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

'UDY: 16 COMPLETENESS: C SOURCE: JPN J CANCER RES 83:31-39
'PE: SHORT TERM YEAR: 1992
'ECIES: RAT LEL: > MG/KG BW/DAY
'RATION: 56 DAYS HNEL: 2500 MG/KG BW/DAY
'FECTS: NO EFFECTS
:TES:
)MMENTS: ONE DOSE LEVEL ONLY; MALES ONLY; TUMOR PROMOTION STUDY
INCREASED SALT INTAKE CAUSED SOME PHYSIOLOGICAL EFFECTS
NO TOXICOLOGICAL EFFECTS

)X 3: GENETIC TOXICITY STUDIES

'UDY: 2A COMPLETENESS: SOURCE:
'PE: YEAR:
'ECIES: LEL: MG/KG BW/DAY
'RATION: HNEL:
'FECTS:
:LLS:
)MMENTS:

9.