

Syn

Allowed

NOSB NATIONAL LIST FILE CHECKLIST

PROCESSING

MATERIAL NAME: Ascorbic Acid

CATEGORY: Synthetic Allowed

Complete?: 3/16

✓

NOSB Database Form

✓

References

✓

MSDS (or equivalent)

✓

FASP (FDA)

✓

Date file mailed out: 2/6/95

TAP Reviews from: _____

Steve Harper, Mark Schwarty

Rich Theuer

✓

Supplemental Information:

Report from Ag Partners of Davis

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 Ascorbic Acid

Type of Use: Crops; Livestock; Processing

TAP Review by:

1. S. Harper
2. m. Schwarty
3. R. Theuer

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: Feb 6

Name of Material: Ascorbic Acid

Reviewer Name: Steven Harper

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

Synthetic compound because of its extraction and purification using synthetic acidulants.

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

Accurate.

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?

No.

Any additional comments or references?

Ascorbic acid has been proven to be non-toxic, necessary in primary food processing and has been historically well accepted by consumers and producers of organic and natural foods.

Signature Steven Harper

Date 3/10/95

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: Feb 6

Name of Material: Ascorbic Acid

Reviewer Name: MARK SCHWARTZ

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

Synthetic

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

Accurate

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?

No

Any additional comments or references?

Signature *Mark Schwartz* Date *2/24/95*

USDA/TAP REVIEWER
COMMENT FORM

Original mailing date: 6 Feb 1995.

Material: Ascorbic Acid (Vitamin C)
Reviewer: Richard C. Theuer

SYNTHETIC Ascorbic acid produced by the major American manufacturers is synthesized by the Reichstein process. D-glucose is hydrogenated to D-sorbitol. D-sorbitol is oxidized microbiologically to L-sorbose. L-sorbose is reacted with acetone to form the 2,3:4,6-bis-diacetone-L-sorbose, which is oxidized and then rearranged by treatment with hydrogen chloride to yield L-ascorbic acid. This synthetic process has been used for almost four decades. Synthetic ascorbic acid is identical in molecular structure and in function to natural ascorbic acid.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Ascorbic acid provides essential vitamin for humans and other primates. As such, it has no universal substitute in food processing. Ascorbic acid is added to many food to fortify them to original, pre-processing Vitamin C levels. Some Federal regulations require Vitamin C fortification (USDA - WIC - infant juice).
2. Ascorbic acid has multiple functional effects. Its antioxidant properties protect fruits from darkening in the presence of oxygen and protect flavor components, fats and oils from oxidation. It is used in flour to improve baking quality.
3. Ascorbic acid is GRAS (Generally Recognized As Safe) as a chemical preservative [21CFR182.3013], dietary supplement [21CFR182.5013], and nutrient [21CFR182.8013], when used in accordance with good manufacturing practice.

The following substance should be added to the National List of Substances as an allowed synthetic ingredient in Organic Food:
ascorbic acid - use should be restricted to dietary supplement and nutrient use for fortifying or enriching foods identified by regulation or professional recommendation as appropriate vehicles for Vitamin C enrichment.

February 22, 1995

Identification

Common Name	Ascorbic Acid	Chemical Name	L-Ascorbic acid
Other Names	Vitamin C, L-3-Ketothreohexuronic Acid Lactone		
Code #: CAS	50-81-7	Code #: Other	CI7650000
N. L. Category	Synthetic Allowed	MSDS	<input checked="" type="radio"/> yes <input type="radio"/> no

Chemistry

Family	
Composition	C ₆ H ₈ O ₆
Properties	Melting point 191 C, specific gravity 1.65. White crystals or powder. Synthetic analog is identical in molecular structure and function to natural.
How Made	Culture fermentation from dextrose. Extracted and purified using synthetic acidulants. The Reichstein process is used in which D-glucose is hydrogenated to D-sorbitol, which is oxidized microbiologically to L-sorbose. L-sorbose is reacted with acetone to form an intermediate which is then oxidized and rearranged by treatment with hydrogen chloride to yield L-ascorbic acid.

Use/Action

Type of Use	Processing
Specific Use(s)	L-Ascorbic acid may be used in soft drinks as an antioxidant for flavor ingredients, in meat and meat-containing products, for curing and pickling, in flour to improve baking quality, in beer as a stabilizer, in fats and oils as an antioxidant, and in a wide variety of foods for vitamin C enrichment. L-Ascorbic acid may also find use in water treatment. Also used as an antioxidant in frozen fruits such as peaches, nectarines, and bananas.
Action	
Combinations	

Status

OFPA	
N. L. Restriction	
EPA, FDA, etc	GRAS
Directions	
Safety Guidelines	
State Differences	
Historical status	
International status	Allowed by European Union and Codex.

OFPA Criteria

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

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

2119(m)3: manufacture & disposal consequences

Typical manufacturing consequences associated with small chemical manufacturing facilities. No disposal problems noted.

2119(m)4: effect on human health

non-toxic. GRAS. Provides an essential vitamin for primates which has no universal substitute in food processing.

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

2119(m)6: alternatives to substance

Fruit juices are alternatives in some situations for antioxidant uses. However, the flavor associated with the fruit juices are not compatible with many uses. While there are some natural sources of vitamin C, none of them is an adequate substitute for nutrient fortification in food processing (because the natural Vitamin C gets lost in the processing conditions. Some federal regulations require Vitamin C fortification.

2119(m)7: Is it compatible?

Traditionally used in the organic foods industry.

References

Furia, T.E. (ed.). CRC Handbook of Food Additives. 2nd ed. Volume 2. Boca Raton, FL; CRC Press, Inc. 1980

Kirk-Othmer Encyclopedia of Chemical Technology. 3rd Edition, vol 24.

&

see attached.

VITAMIN C (Ascorbic Acid) REFERENCES

AU: Bucko,-A; Obonova,-K; Ambrova,-P

TI: The effects of storage and culinary processing on the vitamin C losses in vegetables and potatoes

SO: Nahrung, 1977, 21 (2): 107-112. Ref. Eng. sum.

CN: DNAL 389.8-N142

AU: Birch,-G-G; Bointon,-B-M; Rolfe,-E-J; Selman,-J-D

TI: Quality changes related to vitamin C in fruit juice and vegetable processing

SO: In Vitamin C; recent aspects of its physiological and technological importance. G. G. Birch & K. J. Parker, ed, 1974, p. 40-65. Ref.

CN: DNAL QP772.A8V57

AU: Cook,-D-J

TI: Nutritional losses in food processing--vitamin C

SO: Process-Biochem, June 1974, 9 (5): 21-24.

CN: DNAL TP1.P7

AU: Goldoni,-J.S.; Bonassi,-I.A.; Conceicao,-F.A.D.

TI: Comparative study of vitamin C in cabbage cultivars (*Brassica oleracea* L. var. *capitata* L.) before and after their processing as sauerkraut Ascorbic acid. Estudo comparativo em vitamina C de cultivares de repolho (*Brassica oleracea* L., var. *capitata* L.), antes e depois de seu processamento em chucrute.

SO: Arch-Latinoam-Nutr. Guatemala : Sociedad Latinoamericana de Nutricion. Mar 1983. v. 33 (1) p. 45-55.

CN: DNAL 389.8-AR22

AU: Erdman,-J.W.-Jr.; Klein,-B.P.

TI: Harvesting, processing, and cooking influences on vitamin C in foods Ascorbic acid.

SO: Adv-Chem-Ser. Washington : American Chemical Society. 1982. (200) p. 499-532.

CN: DNAL 381-AD93

AU: Ranken,-M.D.

TI: The use of ascorbic acid in meat processing.

SO: Vitamin C (ascorbic acid) / edited by J.N. Counsell and D.H. Hornig. London; Englewood, N.J. : Applied Science Publishers, c1981. p. 105-122. ill.

CN: DNAL QP772.A8V55-1981

AU: Farhangi,-M.; Valadon,-L.R.G.

TI: Effect of acidified processing and storage on carotenoids (provitamin A) and vitamin C in mung bean sprouts.

SO: J-Food-Sci. Chicago, Institute of Food Technologists. Sept/Oct 1981. v. 46 (5) p. 1464-1466.

CN: DNAL 389.8-F7322

TI: Conserving the nutritive values in foods. Rev. ed.

SO: Hyattsville, MD. : Consumer and Food Economics Institute, 1977. 16 p. : ill. --

CN: TX601.U5-1977-FandN-C-1982

AB: Abstract: The vitamins, minerals, protein and other nutrients in foods can be best preserved through wise handling and preparation. Because vitamin C is more easily destroyed than other food values, retention of vitamin C is often used as an index to the retention of other nutrients. The loss of vitamins during canning has been reduced by improved processing techniques; proper storage of canned goods will conserve nutrients. Freezing offers another good way to retain nutrients, especially vitamin C in frozen fruits. The best ways to conserve the nutritional values in milk, eggs, and cereal products are explored.

AU: Fletcher,-D.L.; Cason,-J.A.

TI: Influence of ascorbic acid on broiler shrink and processing yields.

SO: Poult-Sci. Champaign, Ill. : Poultry Science Association. Oct 1991. v. 70 (10) p. 2191-2196.

CN: DNAL 47.8-AM33P

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: ASCORBIC ACID
FORMULA: HOCH2CH(OH)CHC(OH):C(OH)COO FORMULA WT: 176.12
CAS NO.: 50-81-7 NIOSH/RTECS NO.: CI7650000
COMMON SYNONYMS: L-ASCORBIC ACID; VITAMIN C; L-3-KETOTHREOHEXURONIC ACID
LACTONE
PRODUCT CODES: B581,0937,0936,0938
EFFECTIVE: 05/08/86 REVISION #02

PRECAUTIONARY LABELLING

BAKER SAF-T-DATA(TM) SYSTEM
HEALTH - 1 SLIGHT
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
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: 191 C (376 F) VAPOR DENSITY(AIR=1): N/A
SPECIFIC GRAVITY: 1.65 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE CRYSTALS 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 (IV-MOUSE) (MG/KG) - 518
 CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO
 EFFECTS OF OVEREXPOSURE: NO EFFECTS OF OVEREXPOSURE WERE DOCUMENTED.
 TARGET ORGANS: NONE IDENTIFIED
 MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED
 ROUTES OF ENTRY: NONE INDICATED
 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: AIR, LIGHT
 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, PROPER 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 GENERAL
 CHEMICAL STORAGE AREA.
 KEEP PRODUCT OUT OF LIGHT.

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)

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

ASCORBIC ACID

CAS#: 000050817
 FASP#: 1611
 TYPE: ASP
 NAS#: 2109
 FEMA#: 2109
 GRAS#: 3
 HUMAN CONSUMPTION: 5.5084 MG/KG BW/DAY/PERSON
 MARKET DISAPPEARANCE: 6500000.000 LBS/YR
 MARKET SURVEY: 87
 JECFA: NS-C
 JECFA ADI: 1981 MG/KG BW/DAY/PERSON
 JECFA ESTABLISHED: 931015
 POTENTIAL BEVERAGE USE LAST UPDATE:
 FW: 176.12 DENSITY: LOGP:

STRUCTURE CATEGORIES: C4

COMPONENTS:

SYNONYMS:

VITAMIN C
 ASCORBIC ACID, L-
 CEVITAMIC ACID
 L-ASCORBIC ACID
 KYLOASCORBIC ACID, L-
 HEX-2-ENONIC ACID GAMMA-LACTONE, L-THREO-

CHEMICAL FUNCTION: F

TECHNICAL EFFECT:

NUTRIENT SUPPLEMENT
 ANTIMICROBIAL AGENT
 ANTIOXIDANT
 STABILIZER OR THICKENER
 FLAVOR ENHANCER
 FLAVORING AGENT OR ADJUVANT
 DOUGH STRENGTHENER
 COLOR OR COLORING ADJUNCT
 PH CONTROL AGENT
 SEQUESTRANT

CFR REG NUMBERS:

182.3013	146.113	145.170
145.110	137.200	145.115
182.5013	145.135	161.175
156.145	155.200	137.105
150.161	150.141	146.187
145.116	145.171	145.136
137.205	137.155	182.8013
137.165	137.160	137.170
137.175	137.180	137.185
240.1044		

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1-15 FROM SCOGS-29

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

STUDY: 19 COMPLETENESS: B RANKING FACTOR: 2.203E-3
SPECIES: RAT LEL: 2500 MG/KG BW/DAY
EFFECTS: BODY WEIGHT DECREASE
SITES:
COMMENTS: EFFECT SEEN IN FEMALES ONLY

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

STUDY: 19 COMPLETENESS: B RANKING FACTOR: 2.203E-3
SPECIES: RAT LEL: 2500 MG/KG BW/DAY
EFFECTS: BODY WEIGHT DECREASE
SITES:
COMMENTS: EFFECT SEEN IN FEMALES ONLY

BOX 6: HIGHEST OBSERVED NO-EFFECT LEVEL IN SPECIES OF BOX 4C

STUDY: 19 COMPLETENESS: B LEL: 2500 MG/KG BW/DAY
SPECIES: RAT HNEL: 1250 MG/KG BW/DAY
EFFECTS: BODY WEIGHT DECREASE
COMMENTS: EFFECT SEEN IN FEMALES ONLY

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 1 SOURCE: BIOCHEM J 28:770-773
SPECIES: RAT YEAR: 1934
LD50: 5000 MG/KG BW

COMMENTS: STUDY 1 LD50 = >5000 MG/KG

STUDY: 1 SOURCE: BIOCHEM J 28:770-773
SPECIES: MOUSE YEAR: 1934
LD50: 8000 MG/KG BW

COMMENTS:

STUDY: 1 SOURCE: BIOCHEM J 28:770-773

SPECIES: GUINEA PIG
COMMENTS: STUDY 1 LD50 = >5000 MG/KG

YEAR: 1934
LD50: 5000 MG/KG BW

STUDY: 1
SPECIES: DOG

SOURCE: BIOCHEM J 28:770-773
YEAR: 1934
LD50: 5000 MG/KG BW

COMMENTS: STUDY 1 LD50 = >5000 MG/KG

STUDY: 1
SPECIES: CAT

SOURCE: BIOCHEM J 28:770-773
YEAR: 1934
LD50: 1000 MG/KG BW

COMMENTS: STUDY 1 LD50 = >1000 MG/KG

STUDY: 1
SPECIES: RABBIT

SOURCE: BIOCHEM J 28:770-773
YEAR: 1934
LD50: 2000 MG/KG BW

COMMENTS: STUDY 1 LD50 = >2000 MG/KG

BOX 8: HIGH CONCERN EFFECTS

EFFECT: REPRODUCTIVE TOXICITY
SITE:

SPECIES: GUINEA PIG
LELSTUDY: 5
HNELSTUDY: 5
COMMENTS: DECREASED FERTILITY INDEX
DATA FROM SCOGS-59

RANKING FACTOR: 5.508E-2
LEL: 100 MG/KG BW/DAY
HNEL:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 4
TYPE: SHORT TERM

SPECIES: RAT
DURATION: 70 DAYS
EFFECTS: BODY WEIGHT DECREASE
SITES:

COMPLETENESS:
SOURCE: REV PORT FARM 20:41-46
YEAR: 1970
LEL: 1000 MG/KG BW/DAY
HNEL:

COMMENTS: LAXATIVE EFFECT AT 10000 MG\KG

STUDY: 2
TYPE: SHORT TERM

SPECIES: RAT
DURATION: 70 DAYS
EFFECTS: NO EFFECTS
SITES:

COMPLETENESS:
SOURCE: Z ERNAHR 4:5-14
YEAR: 1963
LEL: > MG/KG BW/DAY
HNEL: 6500 MG/KG BW/DAY

COMMENTS:

STUDY: 6 SOURCE: WISS VEROFF DTSCH GES ERNAHR
14:149-154

COMPLETENESS:

TYPE: SHORT TERM
SPECIES: RAT
DURATION: 42 DAYS
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

YEAR: 1965
LEL: > MG/KG BW/DAY
HNEL: 10000 MG/KG BW/DAY

STUDY: 3 SOURCE: Z ERNAHR 4:5-14

COMPLETENESS:

TYPE: SHORT TERM
SPECIES: RAT
DURATION: 28 DAYS
EFFECTS: MORTALITY INCREASE
SITES:
COMMENTS: 77% MORTALITY AT 23700 MG/KG

YEAR: 1963
LEL: 27300 MG/KG BW/DAY
HNEL: 10000 MG/KG BW/DAY

STUDY: 16 SOURCE: NTP TR 247 (NIH PBL 81-140)

COMPLETENESS: B

TYPE: SHORT TERM
SPECIES: RAT
DURATION: 14 DAYS
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

YEAR: 1983
LEL: > MG/KG BW/DAY
HNEL: 10000 MG/KG BW/DAY

STUDY: 56 SOURCE: TOXICOL LETT 6:309-318

COMPLETENESS: C

TYPE: SHORT TERM
SPECIES: MOUSE
DURATION: 28 DAYS
EFFECTS: NO EFFECTS
SITES:
COMMENTS: MALES ONLY
REPORTING INCOMPLETE

YEAR: 1980
LEL: > MG/KG BW/DAY
HNEL: 625 MG/KG BW/DAY

STUDY: 20 SOURCE: NTP TR 247 (NIH PBL 81-140)

COMPLETENESS: B

TYPE: SHORT TERM
SPECIES: MOUSE
DURATION: 14 DAYS
EFFECTS: NO EFFECTS
SITES:
COMMENTS:

YEAR: 1983
LEL: > MG/KG BW/DAY
HNEL: 15000 MG/KG BW/DAY

STUDY: 7 SOURCE: WISS VEROFF DTSCH GES ERNAHR
14:149-154

COMPLETENESS:

TYPE: SHORT TERM
SPECIES: GUINEA PIG
DURATION: 42 DAYS
EFFECTS: NO EFFECTS
SITES:

YEAR: 1965
LEL: > MG/KG BW/DAY
HNEL: 10000 MG/KG BW/DAY

TYPE: TERATOGENICITY YEAR: 1976 MG/KG BW/DAY
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: 19 DAYS HNEL: 450
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: DAMS EXPOSED DAYS 1-19 OF GESTATION
 TEST COMPOUND = L-ASCORBIC ACID

STUDY: 73 COMPLETENESS: C SOURCE: TOXICOL APPL PHARMACOL
 35:393-395
 TYPE: TERATOGENICITY YEAR: 1976 MG/KG BW/DAY
 SPECIES: GUINEA PIG LEL: 400 MG/KG BW/DAY
 DURATION: 38 DAYS HNEL:
 EFFECTS: PUP WEIGHT AT DAY 0 INCREASE
 PUP MORTALITY DECREASE
 SITES:
 COMMENTS: ONE DOSE LEVEL ONLY; TEST COMPOUND = L-ASCORBIC ACID
 DAMS EXPOSED DAYS 23-50 OF GESTATION

STUDY: 75 COMPLETENESS: C SOURCE: TOXICOL APPL TOXICOL 35:393-395
 TYPE: TERATOGENICITY YEAR: 1976 MG/KG BW/DAY
 SPECIES: HAMSTER LEL: 450 MG/KG BW/DAY
 DURATION: 16 DAYS HNEL: 150
 EFFECTS: PUP WEIGHT AT DAY 0 INCREASE
 SITES:
 COMMENTS: DAMS EXPOSED DAYS 1-15 OF GESTATION
 TEST COMPOUND = L-ASCORBIC ACID

STUDY: 11 COMPLETENESS: SOURCE: ARZNEIM FORSCH 23:1081-1082
 TYPE: TERATOLOGY (PHASE OF REPROD.) YEAR: 1973
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: 22 DAYS HNEL: 1000 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: DAMS EXPOSED DAY 0-21 OF GESTATION

STUDY: 10 COMPLETENESS: SOURCE: ARZNEIM FORSCH 23:1081-1082
 TYPE: TERATOLOGY (PHASE OF REPROD.) YEAR: 1973
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: 10 DAYS HNEL: 1000 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: DAMS EXPOSED DAY 6-15 OF GESTATION

STUDY: 12 COMPLETENESS: SOURCE: ARZNEIM FORSCH 23:1081-1082
 TYPE: TERATOLOGY (PHASE OF REPROD.) YEAR: 1973
 SPECIES: MOUSE LEL: > MG/KG BW/DAY
 DURATION: 10 DAYS HNEL: 1000 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:

Material Report for Ascorbic Acid

Common Name Ascorbic Acid

Other Names Vitamin C; ; 3-keto-L-gulofuranolactone; 3-oxo-L-gulofuranolactone (enol form); Adenex; Allercorb; antiscorbutic vitamin; Ascorvit; C-Vimin; Cantan; Cantaxin; Catavin C; Ce-Vi-Sol; Cebicure; Cebione; Cecon; Cegiolan; Celin; Cergona; Cescorbat; Cetamid; Cevalin; Cevatine; Cevimin; Cevitamic acid; Cevitan; Cevitex; Ciamin; Cipca; Concemin; Davitamon C; L-(+)-ascorbic acid; L-3-ketothreohexuronic acid lactone; L- xyloascorbic acid; Laroscorbine; Lemascorb; Liqui-Cee; Planavit C; Proscorbin; Redoxon; Ribena; Scorbu-C; Testascorbic; Vitacee; Vitacimin; Vitacin; Vitascorbol; Xitix.

Description Ascorbic acid occurs as a white to slightly yellowish crystals or powder with a pleasant, sharp, acidic taste.

Chemical Name L-ascorbic acid

Material Composition C6-H8-O6

CAS# 50-81-7

FEMA# 2109 (Flavor & Extract Manufacturers Association)

Related Materials Ascorbic acid (DL) [CAS# 62624-30-0],
Ascorbic acid (L+) [CAS# 50-81-7]

Regulatory Status

FDA§137.105	Dough conditioner
FDA§137.180	Self rising flour
FDA§137.185	Enriched self-rising flour
FDA§137.200	Whole wheat flour
FDA§145.110	Canned applesauce
FDA§145.115	Canned apricots
FDA§145.135	Canned fruit cocktails
FDA§145.170	Canned peaches
FDA§146.113	Canned fruit nectars
FDA§150.141	Artificially sweetened fruit jelly
FDA§155.200	Certain canned vegetables
FDA§161.175	Frozen raw breaded shrimp
FDA§182.3013	GRAS, flavors useful in acidulants
FDA§182.3013	GRAS, dietary supplement

MID§318.7 To accelerate color fixing in cured pork and beef cuts and cured comminuted meat food products. Product specifications apply.

Use/Action Antioxidant; used as a direct additive or dip. Prevents browning of foods. Also added as a supplemental vitamin to some foods.

Material Report for Ascorbic Acid

Health Concerns

Ascorbic acid is an essential vitamin. Humans are among the few species that cannot synthesize vitamin C, and hence must rely on dietary intake for this essential vitamin. Vitamin C deficiency is commonly called Scurvy. Early symptoms of vitamin C deficiency include; malaise, irritability, emotional disturbances, arthralgia, hyperkeratosis of hair follicles, nosebleeds and petechial hemorrhages. Extreme vitamin C deficiency, if untreated, may result in convulsions, coma, and death.

Ascorbic acid is safe as a food additive. Ascorbic acid is practically non-toxic: probable oral lethal dose (human) above 15 g/kg, more than 1 qt for 70 kg person (150 lb). Human poisonings are unknown and even reliable estimates of lethal dose in animals are rare. Doses on the order of several g on an empty stomach may provoke gastric distress and diarrhea.

The occupational safety and health concerns for ascorbic acid are typical of many low toxicity compounds used in large quantities or high concentrations. Appropriate personal protective equipment and exposure controls must be provided by the employer to protect against acute toxic effects, generally skin, eye or respiratory irritation. Protective equipment and controls might include but not be limited to goggles, respirators, gloves, boots, local exhaust ventilation, containment equipment, fire fighting equipment and eyewash stations. Use of this equipment should be coupled with employee training in regard to good industrial hygiene practices and preparedness in the event of an accidental spill or release. The extent of safety and health requirements are enumerated in state and Federal OSHA standards and regulations.

Production

Domestic production is in the 10 million kilogram range, about half of which is used for food and beverages.

Ascorbic acid is produced in multiple steps beginning with D-glucose hydrogenation to D-sorbitol, in the presence of catalysts, followed by fermentation with *Acetobacter* producing L-sorbose, with which acetone is reacted to produce bis-isopropylidene (alpha)-L-sorbofuranose. Oxidation of which yields bisisopropylidene-2-oxo-L-gulo acid which is hydrolyzed with acid in solvents, and finally purified to yield L-Ascorbic acid.

Environmental Impact

Vitamin C is widely distributed in plants and animals. It is very high in citrus fruits, rosehips, acerola, and fresh tea. Degradative ability (ascorbic acid oxidase) is widespread and thus potential for environmental pollution from vitamin C is slight.

Environmental Impact (cont)

The environmental concerns of an ascorbic acid manufacturing facility are typical of a chemical processing plant. Its operating design must be patterned to conform to environmental protection regulations. Measures must be taken to contain solvents and to keep emissions within official guidelines. Special condensers, continuous instrumental monitoring, and emergency containment and cleanup systems are required. Wastewater-treatment facilities may have to be provided to remove by-product organics and inorganics from effluent streams before disposal. The extent of these treatment facilities depends upon the location of the plant and the local tolerances.

Alternatives

Other antioxidants could replace ascorbic acid for food manufacturing use as an antioxidant. There is no alternative to Vitamin C for supplemental nutritional needs. Vitamin C derived from plant sources is available commercially.

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