~~Non~~
Syn

allowed

NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: Xanthan Gum

CATEGORY: Non-agricultural **Complete?:** _____

✓ NOSB Database Form

✓ References

sent MSDS (or equivalent)

✓ FASP (FDA)

✓ Date file mailed out: 1/8/95

✓ TAP Reviews from: Steven Harper
Richard Theuer
Bob Durst

_____ Supplemental Information:

MISSING INFORMATION: no MSDS available

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 Xanthan Gum

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

TAP Review by:

1. Richard Theuer
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: Xanthan Gum

Reviewer Name: Steven Harper

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

Naturally derived substance.

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

Fairly good

This material should be added to the National List as:

____ **Synthetic Allowed** ____ **Prohibited Natural**

or, X **This material does not belong on the National List because:** Xanthan gum is naturally derived and technically does not involve any synthetic processing.

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?

Because isopropyl alcohol is used to extract and purify this substance it is possible that trace amounts of isopropyl alcohol will remain in the xanthan gum.

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

USDA/TAP Reviewer Comment Form

2.

Material: Xanthan gum

Reviewer: Bob Durst

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

It is a natural compound that is chemically purified. The processing is minimal, but might lead it to being classified as a 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?

Any additional comments or references?

As with all synthetic ingredients, each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.

The following are the only references that deal with the toxicological properties of xanthan. The others all have to do with its physical properties and applications.

AU: Eastwood,-M.A.; Brydon,-W.G.; Anderson,-D.M.W.

TI: The dietary effects of xanthan gum in man.

SO: Food-Addit-Contam-Anal-Surveillance-Eval-Control. London : Taylor & Francis. Jan/Mar 1987. v. 4 (1) p. 17-26. ill., charts.

AB: Abstract: A dietary study assessed the safety of consuming xanthan gum, a high molecular weight exopolysaccharide, as a foodstuffs additive and the effect of its consumption on dietary, biochemical, hematological, and physiological modifications. Perceived beneficial effects on serum cholesterol and fecal bile acids and its moderate bulking effect are noted. No adverse dietary, physiological, or toxicological effects from xanthan gum ingestion were observed. It is

concluded that, as a food additive, xanthan gum is as innocuous as cellulose derivatives, guar gum, locust bean (carob) gum, gum arabic, carrageenan, and pectin.

Woodward, Woodward, McNeely, Kovacs, and Cronin. Tox. and Appl. Pharm. 1973, pp. 30-36. Studies included chronic studies in rats and dogs, and a 3-generation reproduction study in rats.

Signature _____ Date 3/11/95

4.

USDA/TAP REVIEWER COMMENT FORM

Original mailing date: 6 Feb 1995.

Material: Xanthan Gum
Reviewer: Richard C. Theuer

SYNTHETIC Xanthan gum is a polysaccharide gum derived from Xanthomonas campestris by a pure-culture fermentation process and purified by recovery with isopropyl alcohol (NOTE: rubbing alcohol is a 70% isopropyl alcohol solution). It is manufactured as the sodium, potassium or calcium salt. The FDA has established limits on residual isopropyl alcohol in xanthan gum. The microbiological origin would indicate that the material is natural but its manufacture as the sodium, potassium or calcium salt would suggest that it is synthetic. The isopropyl alcohol isolation per se would not make the material synthetic, in this reviewer's judgment.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Production of xanthan gum by fermentation competes with gum production from plant sources (acacia, locust bean/carob, tragacanth, etc.). It is probable that all gums require refining with a solvent such as isopropyl alcohol to achieve adequate purity for food use.
2. Xanthan gum is approved by FDA as a food additive to be used in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent or foam enhancer.

The following substance should be added to the National List of Substances as an allowed synthetic ingredient in Organic Food:

xanthan gum

February 22, 1995

NOSB Materials Database

Identification

Common Name **Xanthan Gum** **Chemical Name**

Other Names

Code #: CAS **Code #: Other**

N. L. Category Non-agricultural **MSDS** ○ yes ○ no

Chemistry

Family

Composition

Properties A high molecular weight polysaccharide gum. Cream-colored powder that is readily soluble in hot or cold water.

How Made Produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris,* purified by recovery with isopropyl alcohol, dried, and milled. Manufactured as the sodium, potassium or calcium salt.

Processing

Use/Action

Type of Use

Specific Use(s) Stabilizer; thickener; emulsifier; suspending agent; foam enhancer.

Action

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc FDA-GRAS

Directions

Safety Guidelines

State Differences

Historical status

International status

NOSB Materials Database

6.

OFPA Criteria

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

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

2119(m)3: manufacture & disposal consequences

None known.

2119(m)4: effect on human health

Non-toxic.

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

2119(m)6: alternatives to substance

Other gums and starches can be used. None give as clean a flavor and texture.

2119(m)7: Is it compatible?

References

See Attached.

AU: Eastwood, -M.A.; Brydon,-W.G.; Anderson,-D.M.W.
TI: The dietary effects of xanthan gum in man.
SO: Food-Addit-Contam-Anal-Surveillance-Eval-Control. London: Taylor & Francis. Jan/Mar 1987. v.4(1) p.17-26.
Abstract: A dietary study assessed the safety of consuming xanthan gum, a gigh molecular weight exopolysaccharide, as a foodstuffs additive and the effect of its consumption on dietary, biochemical, hematological, and physiological modifications. Perceived beneficial effects on serum cholesterol and fecal bile acids and its moderate bulking effect are noted. No adverse dietary, physiological, or toxicological effects from xanthan gum ingestion were observed. It is concluded that, as a food additive, xanthan gum is as innocuous as cellulose derivatives, guar gum, locust bean gum, gum arabic, carrageenan, and pectin.

Woodward, Woodward, McNeely, Kovacs, and Cronin. Tox. and Appl. Pharm. 1973, pp. 30-36. Studies included chronic studies in rats and dogs, and a 3-generation reproduction study in rats.

XANTHAN GUM REFERENCES

AU: El-Salam,-M.H.A.; Fadel,-M.A.; Murad,-H.A.
TI: Bioconversion of sugarcane molasses into xanthan gum.
SO: J-biotechnol. Amsterdam : Elsevier Science Publishers,. Mar 15, 1994. v. 33 (1) p. 103-106.
CN: DNAL QH442.J69

AU: Salcedo,-G.; Ramirez,-M.E.; Flores,-C.; Galindo,-E.
TI: Preservation of Xanthomonas campestris in Brassica oleracea seeds.
SO: Appl-microbiol-biotechnol. Berlin ; New York : Springer International, [1984?-. Sept 1992. v. 37 (6) p. 723-727.
CN: DNAL QR1.E9
AB: Xanthomonas campestris was inoculated into the seeds by incubating, under vacuum, a suspension of the bacteria with the seeds. The seeds were maintained at 4 degrees C during 21 months, during which the viability of the bacteria and their capacity to produce xanthan gum in shake flasks, were evaluated. Bacterial viability showed oscillations but after 20 months it was 10% of the initial. When these seeds were used as a pre-inoculum for a culture to produce xanthan, the final polymer concentration increased slightly with time of seed storage and the final broth viscosity was fairly constant. The method, besides being able to preserve the viability of the bacteria and their ability to produce xanthan in quantity and quality, has the advantages of an easy inoculation procedure, no need for transfers, less contamination risk and improved growth rate of the bacteria in the inoculation medium.

AU: Yaron,-A.; Cohen,-E.; Arad,-S.M.
TI: Stabilization of aloe vera gel by interaction with sulfated polysaccharides from red microalgae and with xanthan gum.
SO: J-agric-food-chem. Washington, D.C. : American Chemical Society. Aug 1992. v. 40 (8) p. 1316-1320.
CN: DNAL 381-J8223
AB: Aloe vera gel was mixed with sulfated polysaccharides isolated from the red microalgae Porphyridium sp., Porphyridium aerugineum, and Rhodella reticulata, with the natural anionic polysaccharide xanthan gum or with nonionic guar gum to determine possible stabilizing effects. It was therefore proposed that the algal polysaccharides or xanthan gum could serve to stabilize the network structure of fresh aloe vera polysaccharides.

AU: Ferrero,-C.; Martino,-M.N.; Zaritzky,-N.E.
TI: Stability of frozen starch pastes: effect of freezing, storage and xanthan gum addition.
SO: J-Food-Process-Preserv. Trumbull, Conn. : Food & Nutrition Press. 1993. v. 17 (3) p. 191-211.
CN: DNAL TX599.J6

AU: Xiong,-Y.; Blanchard,-S.P.
TI: Viscoelastic propeties of myofibrillar protein-polysaccharide composite gels.
SO: J-Food-Sci-Off-Publ-Inst-Food-Technol. Chicago, Ill. : The Institute. Jan/Feb 1993. v. 58 (1) p. 164-167.
CN: DNAL 389.8-F7322
AB: The influence of polysaccharide gums on thermal gelation of chicken salt-soluble protein (SSP) was studied by determining changes in dynamic viscoelasticity and aggregation of the protein-gum composites in 0.6M NaCl at pH 6.0. Xanthan gum increased the storage modulus (G') of SSP up to 45 degrees C, but decreased G' and inhibited the sol leads to gel transition at > 45 degrees C. Alginate generally hindered SSP gelation. SSP-gum composite gels cooled to 23 degrees C were weaker but held more water than gels made from SSP alone.

AU: Hassler,-R.A.; Doherty,-D.H.
TI: Genetic engineering of polysaccharide structure: production of variants of xanthan gum in Xanthomonas campestris.
SO: Biotech-Prog. New York, N.Y. : American Institute of Chemical Engineers. May/June 1990. v. 6 (3) p. 182-187.
CN: DNAL TP248.2.B46

AU: Fu,-J.F.; Tseng,-Y.H.

TI: Construction of lactose-utilizing Xanthomonas campestris and production of xanthan gum from whey.
SO: Appl-Environ-Microbiol. Washington, D.C. : American Society for Microbiology. Apr 1990. v. 56 (4) p. 919-923.
CN: DNAL 448.3-AP5
AB: Xanthomonas campestris pv. campestris possesses a low level of beta-galactosidase and therefore is not able to grow and produce significant amounts of xanthan gum in a medium containing lactose as the sole carbon source. The lacZ gene under the control of the phage promoter was expressed at a high level, enabling the cells to grow in a medium containing lactose. Production of xanthan gum in lactose or diluted whey by the engineered strain was evaluated, and it was found to produce as much xanthan gum in these substrates as the cells did in a medium containing glucose.

AU: Milas,-M.; Rinaudo,-M.; Tinland,-B.
TI: Role of the structure on the rheological behaviour of xanthan gum.
SO: Gums and stabilisers for the food industry, 3 / edited by Glyn O. Phillips, David J. Wedlock, and Peter A. Williams. London : Elsevier Applied Science Publishers, c1986. p. 637-644.
CN: DNAL TP453.C65G862

AU: Webb,-P.G.; Biggs,-R.H.; Gander,-J.E.
TI: Citrus canker--the role of enzymes and xanthan gum in infection and spread of the pathogen.
SO: Proc-Annu-Meet-Fla-State-Hortic-Soc. [S.l.] : The Society. Aug 1988. v. 100 p. 77-78.
CN: DNAL SB319.2.F6F56

AU: Cadmus,-M.C.; Slodki,-M.E.
TI: Bacterial degradation of xanthan gum.
SO: Prog-Biotechnol. Amsterdam : Elsevier Science Publishers B.V. 1987. v. 3 p. 101-107.
CN: DNAL TP248.2.P76

AU: Eastwood,-M.A.; Brydon,-W.G.; Anderson,-D.M.W.
TI: The dietary effects of xanthan gum in man.
SO: Food-Addit-Contam-Anal-Surveillance-Eval-Control. London : Taylor & Francis. Jan/Mar 1987. v. 4 (1) p. 17-26. ill., charts.
CN: DNAL TX553.A3F65
AB: Abstract: A dietary study assessed the safety of consuming xanthan gum as a foodstuffs additive and the effect of its consumption on dietary, biochemical, hematological, and physiological modifications. No adverse dietary, physiological, or toxicological effects from xanthan gum ingestion were observed. It is concluded that, as a food additive, xanthan gum is as innocuous as cellulose derivatives, guar gum, locust bean (carob) gum, gum arabic, carrageenan, and pectin.(wz).

AU: Webb,-P.G.; Biggs,-R.H.; Gander,-J.E.; Meadows,-M.E.
TI: In vivo enhancement of citrus canker symptomatology by xanthan gum interaction.
SO: Proc-Ann-Meet-Fla-State-Hortic-Soc. [s.l.] : The Society. 1986 (pub. 1987). v. 99 p. 211-213.
CN: DNAL SB319.2.F6F56

AU: Vincent,-A.
TI: Fermentation techniques in xanthan gum production.
SO: Top-Enzyme-Ferment-Biotechnol. Chichester : Ellis Horwood. 1985. v. 10 p. 109-145.
CN: DNAL TP248.3.T6

AU: Pettitt,-D.J.
TI: Xanthan gum Food thickeners, Xanthomonas campestris.
SO: Food hydrocolloids / editor, Martin Glicksman. Boca Raton, Fla. : CRC Press, c1982. v.1,p. 127-149. ill.
CN: DNAL TP453.C65F67-1982

AU: Sanderson,-G.R.
TI: The interactions of xanthan gum in food systems Food additive.
SO: Prog-Food-Nutr-Sci. Oxford, Pergamon. 1982. v. 6 p. 77-87. ill.
CN: QP141.A1P72

AU: Teague,-G.D.; Clark,-R.C.; Burgum,-D.R.
TI: Recent developments in the application of xanthan gum in food systems Food additives, bakery products, batter coatings.
SO: Chemistry of foods and beverages : recent developments / edited by George Charalambous and George Inglett. New York : Academic Press, 1982. p. 265-292. ill.
CN: DNAL TX541.C44

AU: Betz,-D.A.
TI: Xanthan gum, a biosynthetic polysaccharide for the food industry.
SO: Food-Technol-Aust. Sydney, Council of Australian Food Technology Associations Jan 1979. v. 31 (1) p. 11-16. ill.
CN: DNAL 389.8-F7333

AU: Frank,-J.F.; Somkuti,-G.A.
TI: General properties of beta-galactosidase of Xanthomonas campestris for production of xanthan gum.
SO: Applied-Environ-Microbiol. Washington, D.C., American Society for Microbiology. Sept/Oct 1979. v. 67 (5) p. 554-556. ill.
CN: DNAL 448.3-AP5

AU: Pettitt,-D.J.
TI: Xanthan gum in food.
SO: Proc-Easter-Sch-Agric-Sci-Univ-Nottingham. London, Butterworths. 1978 (pub. 1979). v. 27 p. 263-282. ill.
CN: DNAL S217.E2

AU: Lawson,-C-J
TI: Production of industrially important gums with particular reference to xanthan gum and microbial alginate
SO: ACS-Symp-Ser-Amer-Chem-Soc, 1977, 41: 282-296.
CN: DNAL QD1.A45

AU: Charles,-M; Radjai,-M-K
TI: Xanthan gum [from Xanthomonas campestris] from acid whey
SO: ACS-Symp-Ser-Amer-Chem-Soc, 1977, 45: 27-39. Ref.
CN: DNAL QD1.A45

AU: Andrew,-T-R
TI: Applications of xanthan gum in foods and related products
SO: ACS-Symp-Ser-Amer-Chem-Soc, 1977, 45: 231-241. Ref.
CN: DNAL QD1.A45
PY: 1977

AU: Cottrell,-I-W; Kang,-K-S
TI: Xanthan gum [fermentation of Xanthomonas campestris], a unique bacterial polysaccharide for food applications [Multipurpose stabilizer, thickener, and processing aid]
SO: Dev-Ind-Microbiol, 1978, 19: 117-131. Ref.
CN: DNAL 448.3-D49

AU: Rocks,-J-K
TI: Xanthan gum
SO: Food-Technol, May 1971, 25 (5): 22-23, 26, 28, 31.
CN: DNAL 389.8-F7398

)CNUM=1563

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

XANTHAN GUM

\S#:	011138662	HUMAN CONSUMPTION:	4.4067	MG/KG BW/DAY/PERSON
\SP#:	1563	MARKET DISAPPEARANCE:	5200000.000	LBS/YR
/PE:	ASP	MARKET SURVEY:	87	
\S#:	0544	JECFA:		
EMA#:		JECFA ADI:		MG/KG BW/DAY/PERSON
RAS#:		JECFA ESTABLISHED:	1991	
		LAST UPDATE:	931215	
V:		DENSITY:	LOGP:	

TRUCTURE CATEGORIES: A9

)MPONENTS:

/NONYMS:

HEMICAL FUNCTION: D

ECHNICAL EFFECT:
STABILIZER OR THICKENER
EMULSIFIER OR EMULSIFIER SALT
TEXTURIZER
FORMULATION AID
SOLVENT OR VEHICLE
ANTICAKING AGENT OR FREE-FLOW AGENT
PROCESSING AID
SURFACE-FINISHING AGENT
COLOR OR COLORING ADJUNCT
DRYING AGENT

FR REG NUMBERS:

133.162	172.695	133.178
133.134	133.133	133.124
133.179	176.170	

INIMUM TESTING LEVEL: 3

OMMENTS:

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

TUDY: 7 COMPLETENESS: B RANKING FACTOR: 2.203E-3
PECIES: RAT LEL: 2000 MG/KG BW/DAY
FFECTS: BODY WEIGHT DECREASE

10.01

)CNUM=1563

[TES:
)MMENTS: EFFECT IN FEMALES ONLY

)X 4B: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE DOG STUDIES

TUDY: 8 COMPLETENESS: B RANKING FACTOR: 8.813E-3
?ECIES: DOG LEL: 500 MG/KG BW/DAY
?FECTS: SOFT STOOL
ITES:
)MMENTS:

)X 4C: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES

TUDY: 8 COMPLETENESS: B RANKING FACTOR: 8.813E-3
PECIES: DOG LEL: 500 MG/KG BW/DAY
FFECTS: SOFT STOOL
ITES:
)MMENTS: SEE BOX 4B

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

TUDY: 8 COMPLETENESS: B LEL: 500 MG/KG BW/DAY
PECIES: DOG HNEL: 250 MG/KG BW/DAY
FFECTS: SOFT STOOL
)MMENTS:

)X 7: ACUTE TOXICITY INFORMATION

TUDY: A-2 SOURCE: FAP 5A1784 5:1038-1040
PECIES: RAT YEAR: 1968
LD50: 4500 MG/KG BW
OMMENTS: STUDY A-2 LD50 = >4500 MG/KG

TUDY: A-1 SOURCE: TOXICOL APPL PHARMACOL 4:487
PECIES: MOUSE YEAR: 1963
LD50: 1000 MG/KG BW
OMMENTS: STUDY A-1 LD50 = >1000 MG/KG

TUDY: A-3 SOURCE: FAP 5A1784 5:1034-1036
PECIES: DOG YEAR: 1968
LD50: 2000 MG/KG BW
OMMENTS: STUDY A-3 LD50 = >2000 MG/KG
