Syn allowed

# NOSB NATIONAL LIST
# FILE CHECKLIST

## PROCESSING

**MATERIAL NAME:** Alginates

**CATEGORY:** Non-agricultural **Complete?:** 3/16

✓ **NOSB Database Form**

✓ **References**

✓ **MSDS (or equivalent)**

✓ **FASP (FDA)**

**Date file mailed out:** 2/14/95

✓ **TAP Reviews from:** Steve Taylor
Rich Thoever

**Supplemental Information:**

① alginic acid
NON allowed

**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** Alginate

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

**TAP Review by:**

1. S. Taylor
2. R. Theuer
3. _____

**Comments/Questions:**

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**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:** 6 Feb

**Name of Material:** Alginates

**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?**

**Any additional comments or references?**

**Signature** Steve Taylor **Date** 3-10-95

2.

# USDA/TAP REVIEWER COMMENT FORM

**Original mailing date: 14 Feb 1995.**

| | | | |
|---|---|---|---|
| Material: | Alginates | Ammonium Alginate | 21CFR184.1133 |
| | | Calcium Alginate | 21CFR184.1187 |
| | | Potassium Alginate | 21CFR184.1610 |
| | | Sodium Alginate | 21CFR184.1724 |

Reviewer: Richard C. Theuer

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**SYNTHETIC** Alginates are produced from alginic acid and various alkaline elements (pH control agents). Alginic acid is a natural constituent of brown algae (brown seaweed). The pH control agents - ammonia, calcium hydroxide, potassium hydroxide, sodium hydroxide - are synthetic, making the alginates synthetic.

Alginic acid itself [21CFR184.1011] is obtained from brown algae by alkaline extraction. Its molecular structure is not altered in this extraction, so it is the opinion of this reviewer that alginic acid is natural.

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COMMENTS RE SECTION 2119(m) CRITERIA:

1. Alginic acid comes from seaweed, a renewable resource, so it is compatible with sustainable agriculture.
2. The amount of alginates are restricted by specific regulations [CFR Title 21, Part 184]. They are widely used in the food industry and have been for about 50 years.
3. All these alginates are Generally Recognized As Safe (GRAS).

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The following substances should be added to the National List of Substances as allowed synthetic ingredients in Organic Food, with uses restricted to those currently approved [CFR Title 21, Part 184]:

| | | |
|---|---|---|
| Alginates: | Ammonium Alginate | 21CFR184.1133 |
| | Calcium Alginate | 21CFR184.1187 |
| | Potassium Alginate | 21CFR184.1610 |
| | Sodium Alginate | 21CFR184.1724 |

The following natural substance should be allowed as an ingredient in organic foods for uses allowed in current regulation. It should not be added to the National List of natural substances prohibited for use as ingredients or processing aids in Organic Food:

| | | |
|---|---|---|
| Alginates: | Alginic Acid | 21CFR184.1011]. |

12 Mar 1995

# NOSB Materials Database

## Identification

**Common Name** **Alginates** **Chemical Name** Alginic acid

**Other Names** Sodium Alginate, Ammonium Alginate, Potassium Alginate, Calcium Alginate, Algin

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

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

## Chemistry

**Family**

**Composition** (C6H3O6)n. Linnear glycuronoglycan consisting mainly of linked D-mannuronic and L-guluronic acid units in the pyranose ring form.

**Properties** Hydrophilic colloidal carbohydrate. White to yellowish white, fibrous powder. Odorless and tasteless. Insoluble in water but readily soluble in alkaline solutions, and insoluble in organic solvents

**How Made** Extracted by the use of a dilute alkali from various species of brown seaweeds (Phaeophyceae). These alkalis (pH control agents) are synthetic: ammonia, calcium hydroxide, potassium hydroxide, sodium hydroxide.

## Use/Action

**Type of Use** Processing

**Specific Use(s)** Stabilizer, thickener, emulsifier.

**Action**

**Combinations**

## Status

**OFPA**

**N. L. Restriction**

**EPA, FDA, etc** FDA-GRAS

**Directions**

**Safety Guidelines**

**State Differences**

**Historical status** Used in food industry for at least 50 years.

**Internationl status** Allowed by European Union 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**

Manufactured from seaweed which is a renewable resource. Chemical used as alkalis may have environmental consequences of production and disposal.

**2119(m)4: effect on human health**

No adverse effects known. Amount in foods is restricted by regulation (CFR Title 21, Part 184) but they are all GRAS.

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

**2119(m)6: alternatives to substance**

Carrageenans, modified celluloses, various plant gums, xanthan gum.

**2119(m)7: Is it compatible?**

Recommendation that alginates be considered compatible synthetics and alginic acid be considered an allowed natural ingredient in processed foods.

## References

See attached.

# ALGINATE REFERENCES

AU: Fumi,-M.D.; Trioli,-G.; Colombi,-M.G.; Colagrande,-O.
TI: Immobilization of Saccharomyces cerevisiae in calcium alginate gel and its application to bottle-fermented sparkling wine production.
SO: Am-J-Enol-Vitic. Davis, Calif. : American Society of Enologists. 1988. v. 39 (4) p. 267-272. ill.
**CN: DNAL 390.9-AM33**

AU: Anderson,-D.M.W.; Andon,-S.A.
TI: Water-soluble food gums and their role in product development.
SO: Cereal-Foods-World. St. Paul, Minn. : American Association of Cereal Chemists. Oct 1988. v. 33 (10) p. 844, 846, 848-850. charts.
**CN: DNAL 59.8-C333**
AB: Abstract: This article discusses gums and their use in food processing. The gums discussed are gum arabic, gum tragacanth, gum karaya, carob, guar gum, agar, alginates, carrageenans, xanthan and carboxymethylcellulose gum. The functions these gums play in product development are discussed.

AU: Oakenfull,-D.
TI: Gelling agents.
SO: C-R-C-Crit-Rev-Food-Sci-Nutr. Boca Raton, Fla. : CRC Press. 1987. v. 26 (1) p. 1-25. ill., charts.
**CN: DNAL TP368.C7**
AB: Abstract: A review article discusses recent developments, relating to gelation, in our understanding of protein-water and polysaccharides-water interactions. Also discussed are new methods for studying gelation and the properties of gels. The various molecular mechanisms by which the polymers in food gels interact to form gel networks are also described. The key to understanding gelation is knowledge of the relationship between the bulk rheological properties of gels and the molecular properties of gel-forming polymers, particularly the means by which the network cross-linkages are formed and stabilized. Specific gel-forming polymers discussed include the carrageenans, alginates, pectins, starch, gelatin and various globular proteins.

AU: Ashton,-W-R
TI: Alginates in the food industry
SO: Afinidad, July/Aug 1975, 32 (328): 653-658.
**CN: DNAL 385-AF4**

AU: McDowell,-R-H
TI: New developments in the chemistry of alginates and their use in food [Additives]
SO: Chem-Ind-Lond, May 3, 1975, 9: 391-395. Ref.
**CN: DNAL 382-M31C**

AU: McNeely,-W-H; Kovacs,-P
TI: The physiological effects of alginates and xanthan gum [Rats]
SO: ACS-Symp-Ser-Amer-Chem-Soc, 1975, 15: 269-281. Ref.
**CN: DNAL QD1.A45**

# MATERIAL SAFETY DATA SHEET
# ALGINIC ACID SODIUM SALT

## SECTION I - Product Identification

PRODUCT NAME: ALGINIC ACID SODIUM SALT
FORMULA: INDEFINITE
FORMULA WT: N/A
CAS NO.:
COMMON SYNONYMS: SODIUM ALGINATE; **ALGIN**

## Precautionary Labeling

N/A

## SECTION II - Hazardous Components

N/A

## SECTION III - Physical Data

BOILING POINT: N/A VAPOR PRESSURE @ 20C (MM HG): N/A
MELTING POINT: INDETERM VAPOR DENSITY (AIR=1): N/A
SPECIFIC GRAVITY: UNAVA EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): SOLUBLE PERCENT VOLATILES BY VOLUME: N/A
APPEARANCE & ODOR: CREAM/TAN COLORED POWDER

## SECTION IV - Fire and Explosion Hazard Data

FLASH POINT: INDETERMINATE
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
FOAM, CO2, DRY POWDER
SPECIAL FIRE-FIGHTING PROCEDURES
WEAR SELF-CONTAINED BREATHING APPARATUS.
UNUSUAL FIRE AND EXPLOSION HAZARDS
NONE

## SECTION V - Health Hazard Data

THRESHOLD LIMIT VALUE (TLV/TWA): NONE ESTABLISHED.
EFFECTS OF OVEREXPOSURE
NONE INDICATED.
EMERGENCY AND FIRST AID PROCEDURES
SKIN CONTACT: WASH WITH SOAP AND WATER
EYE CONTACT: FLUSH WITH WATER
INHALATION: REMOVE TO FRESH AIR.

## SECTION VI - Reactivity Data

STABILITY: UNSTABLE
CONDITIONS TO AVOID: NONE
INCOMPATIBILES: OXIDIZERS, GLYCOL OR DIAMINES (CONTACT MAY CAUSE POLYMERIZATION)

DECOMPOSITION PRODUCTS: COX

## SECTION VII - Spill and Disposal Procedures

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE
TAKE UP AND CONTAINERIZE FOR PROPER DISPOSAL.

## SECTION VIII - Protective Equipment

USE GENERAL EXHAUST VENTILATION.
WEAR PROTECTIVE GLOVES AND SAFETY GOGGLES.

## SECTION IX - Storage and Handling Precautions

AVOID BREATHING DUST.
AVOID CONTACT WITH SKIN AND EYES.

## SECTION X - Transportation Data and Additional Information

NONE

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(TM) and (R) : Registered Trademarks
N/A = Not Applicable OR Not Available
The information published in this Material Safety Data Sheet has been compiled from our experience and data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for adoption of necessary safety precautions. We reserve the right to revise Material Safety Data Sheets periodically as new information becomes available.

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

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ALGINATE, CALCIUM

| | | | | |
|---|---|---|---|---|
| AS#: | 009005350 | HUMAN CONSUMPTION: | 0.3276 | MG/KG BW/DAY/PERSON |
| ASP#: | 1641 | MARKET DISAPPEARANCE: | 386666.666 | LBS/YR |
| YPE: | ASP | MARKET SURVEY: | FDA | |
| AS#: | 2015 | JECFA: | NS-C | |
| EMA#: | 2015 | JECFA ADI: | | MG/KG BW/DAY/PERSON |
| RAS#: | 3 | JECFA ESTABLISHED: | 1992 | |
| OTENTIAL BEVERAGE USE | | LAST UPDATE: | 921015 | |
| W: | | DENSITY: | LOGP: | |

TRUCTURE CATEGORIES: A9

OMPONENTS:

YNONYMS: ALGINIC ACID, CALCIUM SALT

HEMICAL FUNCTION: F

ECHNICAL EFFECT:
STABILIZER OR THICKENER
TEXTURIZER
EMULSIFIER OR EMULSIFIER SALT
FLAVOR ENHANCER
FIRMING AGENT
FORMULATION AID
PROCESSING AID
SURFACE-ACTIVE AGENT

FR REG NUMBERS: 184.1187

INIMUM TESTING LEVEL: 3

OMMENTS: NO TOX STUDIES IN SCOGS-24
NO TOX DATA

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

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ALGINATE, POTASSIUM

| | | | | |
|---|---|---|---|---|
| CAS#: | 009005361 | HUMAN CONSUMPTION: | 0.3276 | MG/KG BW/DAY/PERSON |
| CASP#: | 1642 | MARKET DISAPPEARANCE: | 386666.666 | LBS/YR |
| TYPE: | NEW | MARKET SURVEY: | FDA | |
| EAS#: | | JECFA: | NS-C | |
| FEMA#: | | JECFA ADI: | | MG/KG BW/DAY/PERSON |
| GRAS#: | | JECFA ESTABLISHED: | 1992 | |
| | | LAST UPDATE: | 921015 | |
| MW: | 240000 | DENSITY: | LOGP: | |

STRUCTURE CATEGORIES: A9

COMPONENTS:

SYNONYMS: ALGINIC ACID, POTASSIUM SALT
POTASSIUM POLYALGINATE

CHEMICAL FUNCTION: G

TECHNICAL EFFECT: STABILIZER OR THICKENER
TEXTURIZER
EMULSIFIER OR EMULSIFIER SALT
FLAVOR ENHANCER
FIRMING AGENT
FORMULATION AID
PROCESSING AID
SURFACE-ACTIVE AGENT

CFR REG NUMBERS: 184.1610

MINIMUM TESTING LEVEL: 3

COMMENTS: NO TOX STUDIES IN SCOGS-24
NO TOX DATA

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SCOGS-1643

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

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ALGINATE, SODIUM

| | | | | |
|---|---|---|---|---|
| CAS#: | 009005383 | HUMAN CONSUMPTION: | 0.3276 | MG/KG BW/DAY/PERSON |
| ASP#: | 1643 | MARKET DISAPPEARANCE: | 386666.666 | LBS/YR |
| TYPE: | ASP | MARKET SURVEY: | FDA | |
| CAS#: | 2015 | JECFA: | NS-C | |
| EMA#: | 2015 | JECFA ADI: | | MG/KG BW/DAY/PERSON |
| RAS#: | 3 | JECFA ESTABLISHED: | 1992 | |
| POTENTIAL BEVERAGE USE | | LAST UPDATE: | 921015 | |
| N: | | DENSITY: | LOGP: | |

STRUCTURE CATEGORIES: A9

COMPONENTS:

SYNONYMS:
ALGIN
ALGIN GUM
ALGINIC ACID, SODIUM SALT

CHEMICAL FUNCTION: F

TECHNICAL EFFECT:
STABILIZER OR THICKENER
TEXTURIZER
EMULSIFIER OR EMULSIFIER SALT
FLAVOR ENHANCER
FIRMING AGENT
FORMULATION AID
PROCESSING AID
SURFACE-ACTIVE AGENT

FR REG NUMBERS:

| | | |
|---|---|---|
| 133.133 | 150.161 | 150.141 |
| 133.179 | 133.178 | 133.162 |
| 133.134 | 173.310 | 184.1724 |

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDIES 1-5 FROM SCOGS-24

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

STUDY: 9 COMPLETENESS: C RANKING FACTOR: 8.736E-6

PECIES: MOUSE LEL: 37500 MG/KG BW/DAY
FFECTS: HISTOPATHOLOGY OBSERVATION(S) NOT ELSEWHERE CLASSIFIED
NEPHROSIS
CALCULI
ORGAN DISTENTION
URINE VOLUME INCREASE
URINE SPECIFIC GRAVITY DECREASE
ITES: KIDNEY
URINARY BLADDER
OMMENTS: ONE DOSE LEVEL ONLY; DISTENTION OF RENAL DISTAL TUBULE AND PELVIS INCREASED BLADDER SUBEPITHELIAL INFILTRATION AND INCREASED CYST-LIKE SPACES IN FEMALE KIDNEYS; NEPHROSIS IN MALES RENAL CALCULI IN FEMALES

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

TUDY: 9 COMPLETENESS: C RANKING FACTOR: 0.000E0
PECIES: MOUSE LEL: 37500 MG/KG BW/DAY
FFECTS: HISTOPATHOLOGY OBSERVATION(S) NOT ELSEWHERE CLASSIFIED
NEPHROSIS
CALCULI
ORGAN DISTENTION
URINE VOLUME INCREASE
URINE SPECIFIC GRAVITY DECREASE
BLOOD UREA NITROGEN (BUN) INCREASE
ITES: KIDNEY
URINARY BLADDER
OMMENTS: ONE DOSE LEVEL ONLY; DISTENTION OF RENAL DISTAL TUBULE AND PELVIS INCREASED BLADDER SUBEPITHELIAL INFILTRATION AND INCREASED CYST-LIKE SPACES IN FEMALE KIDNEYS; NEPHROSIS IN MALES RENAL CALCULI IN FEMALES

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OX 7: ACUTE TOXICITY INFORMATION

TUDY: 6 SOURCE: GRM 000140 1:260
PECIES: RAT YEAR: 1972
LD50: 5000 MG/KG BW
OMMENTS: STUDY 6 LD50 = > 5000 MG/KG

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OX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

TUDY: 2 COMPLETENESS: SOURCE: PROC SOC EXP BIOL MED 76:630-635
YPE: SHORT TERM YEAR: 1951