

NOSB NATIONAL LIST FILE CHECKLIST

PROCESSING

MATERIAL NAME: **Kaolin (clay type) & Bentonite**

CATEGORY: **Non-agricultural**

Complete?: _____

NOSB Database Form

References

MSDS (or equivalent) x2

FASP (FDA) (Bentonite)

Date file mailed out: 1/8/95

TAP Reviews from: _____

Richard Thayer

Supplemental Information:

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 Kaolin (clay type) & Bentonite

Type of Use: Crops; Livestock; Processing

TAP Review by:

1. Richard Thayer
2. _____
3. _____

Comments/Questions:

My Opinion/Vote is:

Signature _____ Date _____

USDA/TAP REVIEWER
COMMENT FORM

1.

Original mailing date: 14 Feb 1995.

Material: Clays

Kaolin (China clay) 21CFR186.1256
Bentonite 21CFR184.1155

Reviewer: Richard C. Theuer

NATURAL

Kaolin and bentonite are natural clays. Kaolin occurs in largely deposits of relatively pure kaolinite. Clays consist of alumina, silica and water. Clay can calcined in a kiln to produce a fine powder. The fine particles provide large total surface area and, hence, pronounced adsorptive capability.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. Clay is a natural material. It is mined resource. Mining usually has negative environmental impact.
2. Bentonite is used as a processing aid, not as an ingredient.
3. Current good manufacturing practice for bentonite results in no significant residue in the food.
4. Clay has no human toxicity at low levels of intake. Geophagia (excessive intakes of clay), particularly during pregnancy, can cause iron deficiency anemia.
5. Kaolin is allowed as a GRAS indirect human food ingredient. It is used in the manufacture of paper and paperboard that contact food.

The following natural substances should be allowed in the processing or packaging of organic foods. They should not be added to the National List of natural substances prohibited for use as ingredients or processing aids in Organic Food:

clays: kaolin
bentonite

12 Mar 1995

NOSB Materials Database

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Identification

Common Name **Kaolin (Clay) & Bentonite** **Chemical Name**
Other Names China clay, argilla; also Bentonite
Code #: CAS **Code #: Other**
N. L. Category Non-agricultural **MSDS** yes no

Chemistry

Family
Composition Kaolin is a purified clay consisting mainly of alumina, silica, and water. Bentonite is a porous rock of clay minerals derived from weathered volcanic ash or tuff.
Properties A fine, white to yellowish white or grayish aluminum silicate clay with low shrink-swell potential. It becomes darker and has a distinct claylike odor when moistened. Insoluble in water, in alcohol, in dilute acids, and in alkali solutions.
How Made Mined. Can be calcined in a kiln to produce a fine powder. Natural.

Processing

Use/Action

Type of Use
Specific Use(s) Kaolin: Anticaking agent. Bentonite: clarifying or refining wines and fruit juices. Processing aid; not present in final product.
Action Large total surface area creates pronounced adsorptive capability.
Combinations

Status

OFPA
N. L. Restriction
EPA, FDA, etc
Directions
Safety Guidelines
State Differences
Historical status
International status

OFPA Criteria

2119(m)1: chemical interactions Not Applicable

2119(m)2: toxicity & persistence Not Applicable

2119(m)3: manufacture & disposal consequences

Similar to other mining operations.

2119(m)4: effect on human health

Kaolin is GRAS and clays do not have any human toxicity at low intake levels.

2119(m)5: agroecosystem biology Not Applicable

2119(m)6: alternatives to substance

unknown.

2119(m)7: Is it compatible?

References

AU: Permual,-D.; Le-Patourel,-G.

TI: Small bin trials to determine the effectiveness of acid-activated kaolin against four species of beetles infesting paddy under tropical storage conditions.

SO: J-Stored-Prod-Res. Exeter : Pergamon Press. July 1992. v. 28 (3) p. 193-199.

CN: DNAL 421-J829

AB: Control of populations of *Rhizopertha dominica*, *Sitophilus oryzae*, *Tribolium castaneum* and *Oryzaephilus surinamensis* infesting paddy treated with acid-activated kaolin (AAK) at 0.75% w/w or with pirimiphos-methyl (PM) diluted with AAK to give 2 mg PM/kg paddy was compared with that in untreated paddy or paddy admixed with a 2% PM dust formulation on tale at 8 mg a.i./kg. All three treatments controlled adult populations of the insects up to 200 days post-treatment, but *R. dominica* populations started to increase at 250 days in the treatment using 2% PM dust, and this treatment gave progressively lower mortality of *R. dominica* and less suppression of progeny development in 7 day bioassays using samples taken through the trial than the other treatments.

UD: 9112

TI: Phenolic compounds and polyphenoloxidase in relation to browning in grapes and wines.

XAU: Universite Montpellier, Montpellier, France.

UD: 8906

TI: Adsorption of protein by bentonite in a model wine solution.

DE: wines-. protein-content. winemaking-residues. adsorption-. bentonite-. temperature-. ethanol-. ph-. cation-exchange-capacity. solutions-. purification-. food-processing.

UD: 8902

TI: A comparison of the use of chitosan and gelatin on the clarification of five blends of apple juice using both hot and cold treatment methods.

DE: apple-juice. food-processing. clarification-. gelatin-. chitosan-. bentonite-. color-.

AU: Dawes,-H.; Struebi,-P.; Boyes,-S.; Heatherbell,-D.

TI: Kiwifruit proteins: characterization and removal during processing of clarified juice.

SO: Acta-Hortic. Wageningen : International Society for Horticultural Science. Apr 1992. v. 2 (297) p. 667-674.

CN: DNAL 80-AC82

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: KAOLIN
FORMULA: AL2O3 2SiO2 2H2O
CAS NO.: 01332-58-7
COMMON SYNONYMS: KAOLINITE; CHINA CLAY; BOLUS ALBA; PORCELAIN CLAY
PRODUCT CODES: 2242,2240
EFFECTIVE: 06/30/86
REVISION #02

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

Table with 3 columns: COMPONENT, %, CAS NO. Row 1: KAOLIN, 90-100, 1332-58-7

3 - PHYSICAL DATA

BOILING POINT: N/A
MELTING POINT: N/A
SPECIFIC GRAVITY: 2.60 (H2O=1)
VAPOR PRESSURE(MM HG): N/A
VAPOR DENSITY(AIR=1): N/A
EVAPORATION RATE: N/A (BUTYL ACETATE=1)
SOLUBILITY(H2O): NEGLIGIBLE (LESS THAN 0.1 %)
% VOLATILES BY VOLUME: 0
APPEARANCE & ODOR: WHITE TO YELLOWISH OR GRAY 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.

5 - HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE (TLV/TWA): 10 MG/M3 (PPM)
SHORT-TERM EXPOSURE LIMIT (STEL): 20 MG/M3 (PPM)

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

EFFECTS OF OVEREXPOSURE

INHALATION OF DUST MAY CAUSE IRRITATION TO UPPER RESPIRATORY TRACT.

PROLONGED CONTACT MAY CAUSE SKIN IRRITATION.

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: NONE DOCUMENTED

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: RESPIRATORY PROTECTION REQUIRED IF AIRBORNE CONCEN-
TRATION EXCEEDS TLV. AT CONCENTRATIONS ABOVE 10 MG/M3, A DUST/MIST
RESPIRATOR IS RECOMMENDED.

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 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)

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MATERIAL SAFETY DATA SHEET
BENTONITE

SECTION I - Product Identification

PRODUCT NAME: BENTONITE
COMPANY NAME: SIGMA CHEMICAL COMPANY
DATE: 10/13/87
EMERGENCY TELEPHONE: (314) 771-5765
RTECS: CT9450000
CAS #: 1302-78-9
SYNONYMS: NDA

SECTION II - Hazardous Components

NA

SECTION III - Physical Data

MP: NDA
BP: NDA
APPEARANCE & ODOR: POWDER

SECTION IV - Fire and Explosion Hazard Data

EXTINGUISHING MEDIA: ...
WATER SPRAY.
CARBON DIOXIDE, DRY CHEMICAL POWDER, ALCOHOL OR POLYMER FOAM.
SPECIAL FIREFIGHTING PROCEDURES: WEAR SELF-CONTAINED BREATHING APPARATUS AND
PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
NDA

SECTION V - Health Hazard Data

ACUTE EFFECTS: MAY BE HARMFUL BY INHALATION, INGESTION, SKIN ABSORPTION.
CAUSES EYE AND SKIN IRRITATION.
CAUSES IRRITATION TO MUCOUS MEMBRANES, UPPER RESPIRATORY TRACT.
TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL/PHYSICAL/TOXICOLOGICAL
PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED.
FIRST AID PROCEDURES:
IMMEDIATELY FLUSH EYES OR SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST
15 MINUTES; ASSURE ADEQUATE FLUSHING BY SEPARATING EYELIDS WITH FINGERS.
IF INHALED, REMOVE TO FRESH AIR.
IF BREATHING IS DIFFICULT, CALL A PHYSICIAN.
INGESTION: WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.
CALL A PHYSICIAN !!!
CONTAMINATED CLOTHING & SHOES: REMOVE

SECTION VI - Reactivity Data

STABILITY: STABLE
HAZARDOUS COMBUSTION:
NATURE OF DECOMPOSITION PRODUCTS NOT KNOWN
HAZARDOUS POLYMERIZATION: WILL NOT OCCUR

INCOMPATIBILITIES:
NDA

SECTION VII - Spill and Disposal Procedures

SPILLED MATERIAL: EVACUATE AREA. SHUT OFF ALL SOURCES OF IGNITION.
WEAR CHEMICAL SAFETY GOGGLES, RUBBER BOOTS, HEAVY RUBBER GLOVES.
WEAR SELF-CONTAINED BREATHING APPARATUS.
AVOID RAISING DUST.
VENTILATE AREA & WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.
SWEEP UP OR PICK UP & PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
DISPOSAL: INCINERATOR
CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.
OBSERVE ALL FEDERAL, STATE AND LOCAL LAWS.

SECTION VIII - Protective Equipment

EYES: SAFETY GOGGLES
SKIN: CHEMICAL RESISTANT GLOVES, CLOTHING
VENTILATION: MECHANICAL EXHAUST
RESPIRATOR: NIOSHA/MSHA-APPROVED RESPIRATOR
OTHER: SAFETY SHOWER AND EYE WASH.
FULL PROTECTIVE CLOTHING.

SECTION IX - Storage and Handling Precautions

STORAGE PRECAUTIONS: DO NOT GET IN EYES, SKIN, CLOTHING. DO NOT PIPET BY MOUTH.
DO NOT BREATHE VAPOR.
KEEP TIGHTLY CLOSED.
WASH THOROUGHLY AFTER HANDLING.
WATER AND SEEK MEDICAL ADVICE.
WEAR SUITABLE PROTECTIVE CLOTHING.
STORE IN A COOL DRY PLACE.

SECTION X - Transportation Data and Additional Information

TOXICITY DATA:
ORL-RAT LD50 (MG/KG): NDA
IHL-RAT LD50 (MG/KG): NDA
SCU-RBT LD50 (MG/KG): NDA
ORL-HMN LDLO (MG/KG): NDA

(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.

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DCNUM=1754

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

BENTONITE

| | | | | |
|-------|-----------|-----------------------|-------------|---------------------|
| AS#: | 001302789 | HUMAN CONSUMPTION: | 3.4039 | MG/KG BW/DAY/PERSON |
| ASP#: | 1754 | MARKET DISAPPEARANCE: | 4016666.666 | LBS/YR |
| TYPE: | ASP | MARKET SURVEY: | 87 | |
| AS#: | 0028 | JECFA: | | |
| EMA#: | | JECFA ADI: | | |
| IAS#: | | JECFA ESTABLISHED: | | |
| | | LAST UPDATE: | 931015 | MG/KG BW/DAY/PERSON |

4: DENSITY: LOGP:

STRUCTURE CATEGORIES: C51

COMPONENTS:

SYNONYMS:

CHEMICAL FUNCTION: G

TECHNICAL EFFECT:
DOUGH STRENGTHENER
FLOUR TREATING AGENT
OXIDIZING OR REDUCING AGENT
PROCESSING AID
STABILIZER OR THICKENER

| | | | |
|-----------------|----------|---------|---------|
| FR REG NUMBERS: | 184.1155 | 175.105 | 175.300 |
| | 176.170 | | |

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDIES 2 TO 4 FROM SCOGS-90

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

| | | | |
|-----------|----------------------|---------------|--------------------------|
| STUDY: | 3 | COMPLETENESS: | RANKING FACTOR: 4.538E-5 |
| SPECIES: | MOUSE | LEL: | 75000 MG/KG BW/DAY |
| EFFECTS: | BODY WEIGHT DECREASE | | |
| ORGANES: | FATTY INFILTRATION | | |
| | LIVER | | |
| COMMENTS: | DATA FROM SCOGS-90 | | |

OCNUM=1754

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

TUDY: 3 COMPLETENESS: RANKING FACTOR: 4.538E-5
 PECIES: MOUSE
 FFECTS: BODY WEIGHT DECREASE LEL: 75000 MG/KG BW/DAY
 ITES: FATTY INFILTRATION
 LIVER
 OMMENTS: DATA FROM SCOGS-90

OX 7: ACUTE TOXICITY INFORMATION

TUDY: 1 SOURCE: CMF 000009 43:011422
 PECIES: RAT YEAR: 1970
 LD50: 5000 MG/KG BW
 OMMENTS: STUDY 1 LD50 > 5000 MG/KG
 MALES ONLY

OX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

TUDY: 2 COMPLETENESS: SOURCE: CAN J BIOCHEM PHYSIOL
 YPE: SHORT TERM YEAR: 1954
 PECIES: RAT LEL: 400 MG/KG BW/DAY
 URATION: 28 DAYS HNEL:
 FFECTS: HISTOPATHOLOGY OBSERVATION(S) NOT ELSEWHERE CLASSIFIED
 ITES: LIVER
 OMMENTS: ANIMALS PREVIOUSLY ON VITAMIN A DEFICIENT DIET
 VITAMIN A ADSORBED TO BENTONITE
 TEST COMPOUND SODIUM BENTONITE
 DECREASED LEVEL OF VITAMIN A IN THE LIVER
 NOT USED FOR PRIORITY RANKING

TUDY: 3 COMPLETENESS: SOURCE: J NATL CANCER INST 14:57-63
 YPE: SHORT TERM YEAR: 1953
 PECIES: MOUSE LEL: 75000 MG/KG BW/DAY
 URATION: 60 DAYS HNEL: 37500 MG/KG BW/DAY
 FFECTS: BODY WEIGHT DECREASE
 FATTY INFILTRATION
 ITES: LIVER
 OMMENTS: ANIMALS DEVELOPED SIGNS OF DECREASED CHOLINE DEFICIENCY
 EFFECT DUPLICATED IN 1965 RUSSIAN STUDY OF UNKNOWN DURATION

OX 3: GENETIC TOXICITY STUDIES