

# 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:

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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

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**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 be calcined in a kiln to produce a fine powder. The fine particles provide large total surface area and, hence, pronounced adsorptive capability.

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**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.

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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 *Rhyzopertha 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

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**SECTION VII - Spill and Disposal Procedures**

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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.

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**SECTION VIII - Protective Equipment**

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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.

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**SECTION IX - Storage and Handling Precautions**

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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.

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**SECTION X - Transportation Data and Additional Information**

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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

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(TM) and (R) : Registered Trademarks

N/A = Not Applicable OR Not 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:		MG/KG BW/DAY/PERSON
		LAST UPDATE:	931015	

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