NOSB NATIONAL LIST
FILE CHECKLIST

PROCESSING

MATERIAL NAME: Silicon Dioxide

CATEGORY: Non-agricultural **Complete?:** 3/17

✓ NOSB Database Form

____ References

✓ MSDS (or equivalent)

✓ FASP (FDA)

✓ Date file mailed out: 2/14/95

✓ TAP Reviews from:
Steve Taylor
Bob Durst

____ Supplemental Information:

Tabled further info

MISSING INFORMATION: another TAP review from Rich Theuer

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 Silicon Dioxide

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

TAP Review by:

1. Steve Taylor
2. Bob Durst
3.

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: 14 Feb

Name of Material: Silicon Dioxide

Reviewer Name: Steve Taylor

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

Synthetic

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** 3-5-95

USDA/TAP Reviewer Comment Form

2.

Material: Silicon Dioxide

Reviewer: Bob Durst

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

Commercially it is a produced in a synthetic manner and thus should be classified as 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:

_____ Synthetic Allowed,

__X__ 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?

There are questions in the literature about the safety of this compound. Until these are resolved, and it is shown to be non-toxic, and also non-hazardous to handlers, it should not be allowed.

Any additional comments or references?

AU: Peluso,-M.R.; Schneeman,-B.O.

TI: A food-grade silicon dioxide is hypocholesterolemic in the diet of cholesterol-fed rats.

SO: J-nutr. Bethesda, Md. : American Institute of Nutrition. June 1994. v. 124 (6) p. 853-860.

CN: DNAL 389.8-J82

AB: Silicon dioxide, commonly referred to as silica, is present in plant cell walls and interstitial spaces, and is often found as a component of dietary fibers that have exhibited hypocholesterolemic activity in animals. The primary objective of this study was to determine the cholesterolemic effects of two different morphological forms of silicon in the diet of cholesterol-fed rats. Male Wistar rats were provided diets containing 1 g cholesterol/100 g diet, and 0.65 g Si/100 g diet as either a sodium salt (silicate group) or silicon dioxide, a synthetic silica polymer (silica group). Cellulose was used as a control (control group). The in vitro bile acid binding capacity of the SiO2 was also measured. After 44 d of diet administration, animals were deprived of food for 24 h and then killed. Plasma total, VLDL, and LDL cholesterol concentrations were 18%, 29%, and 26% lower, respectively, in the silica group than in the control group. However, liver cholesterol concentrations were not different among dietary treatments. During the initial 15 d of the study, average daily total fecal bile acids were 38%

higher in the silica group than in the control group, but fecal bile acid outputs were not different for the remainder of the experiment. The silica polymer used in the feeding trial was found to adsorb 5 times more cholate than chenodeoxycholate, at pH 7.5 in vitro. In vivo, the potential for silica to enhance fecal cholic acid excretion, relative to chenodeoxycholic acid during the initial stage of the study, may have contributed to the hypocholesterolemic response to the silica diet. It is further hypothesized that normalization of fecal bile acid levels in the silica group may have been due to an adaptation response that involved changes in the spectrum of bile acids in the enterohepatic pool.

AU: Villota,-R.; Hawkes,-J.G.

TI: Food applications and the toxicological and nutritional implications of amorphous silicon dioxide.

SO: C-R-C-Crit-Rev-Food-Sci-Nutr. Boca Raton, Fla. : CRC Press. 1986. v. 23 (4) p. 289-321. ill., charts.

AB: Abstract: A literature review provides current information on the incorporation of amorphous silicon dioxide (silica) as a functional additive in food processing, and discusses some of the toxicological and nutritional aspects of silica usage. The differences between silicas and their surface chemistry are considered with respect to their rheological and toxicological behavior and to possible mechanisms of actions with food components. Specific attention is given to fumed silica and its food applications. Data on the physical properties of commercial conditioning agents (including silicas) and on current commercial applications of amorphous silica are included.(wz).

Signature _____ Date 3/4/95

NOSB Materials Database

Identification

Common Name **Silicon Dioxide**

Chemical Name

Other Names Synthetic Amorphous Silica

Code #: CAS

Code #: Other

N. L. Category Non-agricultural

MSDS ◉ yes ○ no

Chemistry

Family

Composition SiO_2

Properties Amorphous substance with noncrystalline pattern. Fumed silica is a white, fluffy, nongritty powder and is hygroscopic. Wet-process silicas occur as white, fluffy powders or as microcellular granules and are hygroscopic or absorb moisture from the air. All are insoluble in water and in organic solvents, but are soluble in hydrofluoric acid and in hot, concentrated solutions of alkalies.

How Made "produced synthetically by either a vapor-phase hydrolysis process, yielding *fumed* (or colloidal) *silica*, or by a wet process, yielding *precipitated silica, silica gel,* or *hydrous silica.*" (FCC)

Processing

Use/Action

Type of Use

Specific Use(s) Anticaking agent; defoaming agent; carrier; conditioning agent; chillproofing agent in malt beverages.

Action

Combinations

Status

OFPA

N. L. Restriction

EPA, FDA, etc FDA-GRAS

Directions

Safety Guidelines

State Differences

Historical status

Internationl status Allowed by EU 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

2119(m)4: effect on human health

Safety is questioned in some literature. See TAP review by Bob Durst.

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

2119(m)6: alternatives to substance

Other anticaking agents.

2119(m)7: Is it compatible?

References

AU: Villota,-R.; Hawkes,-J.G.
TI: Food applications and the toxicological and nutritional implications of amorphous silicon dioxide.
SO: C-R-C-Crit-Rev-Food-Sci-Nutr. Boca Raton, Fla. : CRC Press. 1986. v. 23 (4) p. 289-321. ill., charts.
CN: DNAL TP368.C7
AB: Abstract: A literature review provides current information on the incorporation of amorphous silicon dioxide (silica) as a functional additive in food processing, and discusses some of the toxicological and nutritional aspects of silica usage. Data on the physical properties of commercial conditioning agents (including silicas) and on current commercial applications of amorphous silica are included.(wz).

AU: Peleg,-Micha.; Hollenbach,-Ann-M.
TI: Flow conditioners and anticaking agents.
SO: Food-Technol. Chicago, Ill. : Institute of Food Technologists. March 1984. v. 38 (3) p. 93-102.
CN: DNAL 389.8-F7398
AB: Abstract: Flow conditioners and anticaking agents are finely-divided solids that are added to a host powder to improve its flowability and/or to inhibit its tendency to cake. The principal commercial food-grade conditioners include silicon dioxide, silicates, phosphates, stearic acid salts, talcum, starches, and modified carbohydrates. Varying the concentration of these additives can produce certain effects.

TI: New vitamin E dispersant proposed by USDA.
SO: Sch-Foodserv-J. Denver, Colo. : American School Food Service Association. Mar 1987. v. 41 (3) p. 30.
CN: DNAL 389.8-SCH6
AB: Abstract: Silicon dioxide, a crystallized mineral, can disperse water-insoluble substances (such as vitamin E) in water. The USDA is proposing that it be used in the curing of bacon, to help distribute vitamin E more evenly in the curing solutions for pumped bacon. Vitamin E is important in cured bacon because it helps prevent the formation of nitrosamines when bacon is fried.

See attached TAP review by Bob Durst for more citations.

MATERIAL SAFETY DATA SHEET
T.H.E. DESICCANT, INDICATING GRADE

SECTION I - Product Identification

PRODUCT NAME: T.H.E. DESICCANT, INDICATING GRADE
FORMULA: SIO2
FORMULA WT: N/A
CAS NO.:
COMMON SYNONYMS: SILICON DIOXIDE

Precautionary Labeling

N/A

SECTION II - Hazardous Components

N/A

SECTION III - Physical Data

BOILING POINT: UNAVA VAPOR PRESSURE @ 20C (MM HG): UNAVA
MELTING POINT: 1710C VAPOR DENSITY (AIR=1): UNAVA
SPECIFIC GRAVITY: 2.2 EVAPORATION RATE: N/A
(H2O=1) (BUTYL ACETATE=1)
SOLUBILITY(H2O): INSOLUBLE PERCENT VOLATILES BY VOLUME: UNAVA
APPEARANCE & ODOR: WHITE AND BLUE ODORLESS BEADS

SECTION IV - Fire and Explosion Hazard Data

FLASH POINT: NONFLAMMABLE
FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
FIRE EXTINGUISHING MEDIA
ANY SUITABLE FOR OTHER MATERIALS INVOLVED
SPECIAL FIRE-FIGHTING PROCEDURES
WEAR SELF-CONTAINED BREATHING APPARATUS
UNUSUAL FIRE AND EXPLOSION HAZARDS
NONE INDICATED

SECTION V - Health Hazard Data

THRESHOLD LIMIT VALUE (TLV/TWA): 0.1 MG/M3
EFFECTS OF OVEREXPOSURE
EYE CONTACT CAUSES IRRITATION. PROLONGED OR REPEATED BREATHING OF DUST CAN CAUSE LUNG DAMAGE (PULMONARY FIBROSIS)
EMERGENCY AND FIRST AID PROCEDURES
SKIN: WASH WITH SOAP/WATER; GET MEDICAL ASSISTANCE FOR } PERSISTENT DERMATITIS
EYES: FLUSH THOROUGHLY WITH WATER FOR 15 MINUTES; GET MEDICAL ASSISTANCE
INHALATION: REMOVE TO FRESH AIR; GET MEDICAL ASSISTANCE
INGESTION: GET MEDICAL ASSISTANCE
GET MEDICAL ASSISTANCE FOR ALL CASES OF OVEREXPOSURE

SECTION VI - Reactivity Data

STABILITY: STABLE
CONDITIONS TO AVOID: NONE

INCOMPATIBILES: HF, STRONG ALKALIES
DECOMPOSITION PRODUCTS: NONE KNOWN

SECTION VII - Spill and Disposal Procedures

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE
SWEEP UP & CONTAINERIZE FOR PROPER DISPOSAL

SECTION VIII - Protective Equipment

PROVIDE ADEQUATE GENERAL MECHANICAL VENTILATION
PROTECT EYES AND SKIN WITH SAFETY GOGGLES AND GLOVES
WEAR DUST MASK OR CARTRIDGE RESPIRATOR IF DUST CONCENTRATION IS UNACCEPTABLY HIGH
DO NOT BREATHE DUST

SECTION IX - Storage and Handling Precautions

KEEP CONTAINER TIGHTLY CLOSED WHEN NOT IN USE
STORE IN A COOL, DRY, WELL-VENTILATED AREA AWAY FROM INCOMPATIBLE MATERIALS
WASH THOROUGHLY AFTER HANDLING

SECTION X - Transportation Data and Additional Information

INDICATING GRADES CONTAIN A VERY SMALL AMOUNT OF COBALTOUS CHLORIDE INDICATOR WHICH DOES NOT AFFECT HAZARD DATA OR INFORMATION

(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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CNUM=1393

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

SILICON DIOXIDE

S#:	007631869	HUMAN CONSUMPTION:	9.7330	MG/KG BW/DAY/PERSON
SP#:	1393	MARKET DISAPPEARANCE:	11485000.000	LBS/YR
PE:	ASP	MARKET SURVEY:	87	
S#:	1158	JECFA:	NS-C	
MA#:		JECFA ADI:		MG/KG BW/DAY/PERSON
AS#:		JECFA ESTABLISHED:	1985	
		LAST UPDATE:	931215	
:	60.09	DENSITY:	LOGP:	

RUCTURE CATEGORIES: B1

MPONENTS:

NONYMS: SILICON DIOXIDE

EMICAL FUNCTION: F

CHNICAL EFFECT:
ANTICAKING AGENT OR FREE-FLOW AGENT
DRYING AGENT
HUMECTANT
FORMULATION AID
LUBRICANT OR RELEASE AGENT
SOLVENT OR VEHICLE
ANTIOXIDANT
FLAVORING AGENT OR ADJUVANT
EMULSIFIER OR EMULSIFIER SALT
COLOR OR COLORING ADJUNCT

R REG NUMBERS:

182.90	172.480	173.340
172.230	160.105	133.146
160.185	73.1	573.940
175.105		

NIMUM TESTING LEVEL: 3

MMENTS: COMPOUND = SAND
SEE MEMO FASP SECTION A DATED 05/02/83

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

8.

CNUM=1393

UDY: 7 COMPLETENESS: C RANKING FACTOR: 1.946E-3>
ECIES: RAT LEL: >5000 MG/KG BW/DAY
FECTS: NO EFFECTS
TES:
MMENTS: HIGHEST DOSE TESTED

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

UDY: 1 COMPLETENESS: C RANKING FACTOR: 1.216E-2>
ECIES: DOG LEL: >800 MG/KG BW/DAY
FECTS: NO EFFECTS
TES:
MMENTS: HIGHEST DOSE TESTED IN 28-DAY STUDY USE R FOR PRIORITY SETTING OF SHORTTERM STUDIES

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

UDY: 7 COMPLETENESS: C RANKING FACTOR: 1.946E-3>
ECIES: RAT LEL: >5000 MG/KG BW/DAY
FECTS: NO EFFECTS
TES:
MMENTS: HIGHEST DOSE TESTED

X 7: ACUTE TOXICITY INFORMATION

UDY: 8 SOURCE: FAP 1A0303 1:12
ECIES: RAT YEAR: 1958
LD50: 3160 MG/KG BW

MMENTS: STUDY 8 LD50 = >3160 MG/KG

X 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

UDY: 1 COMPLETENESS: C SOURCE: PROC NATL ACAD SCI 65:872-875
PE: SHORT TERM YEAR: 1970
ECIES: DOG LEL: > MG/KG BW/DAY
RATION: 28 DAYS HNEL: 800 MG/KG BW/DAY
FECTS: NO EFFECTS
TES:
MMENTS: HIGHEST DOSE TESTED

UDY: 7 COMPLETENESS: C SOURCE: FAP 1A0303 1:29-64