



02-11-10 P12:29 IN

January 20, 2010

Mr. Miles McEvoy,  
Deputy Administer National Organic Program  
Room 4008-So., Ag Stop 0268  
1400 Independence Ave., SW  
Washington, DC 20250

Re: Petition to Remove a Synthetic Non-Agricultural Substance from the National List

Dear Mr. McEvoy:

Please accept this Petition to remove "Silicon Dioxide" from the list of synthetic non-agricultural substances allowed under 7 CFR 205.605(b) as ingredients in or on processed food labeled as "organic" or "made with organic". It is the petitioner's belief that the exemption given to place Silicon Dioxide on the National List is no longer valid. According to the Organic Food Production Act of 1990 (OFPA), at 7U.S.C 6517 National List, "(a) in general The Secretary shall establish a National List of approved and prohibited substances... (c) Guidelines for prohibitions or exemptions (1) Exemption for prohibited substances The National List may provide for use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter **only if-** (A) the Secretary determines, ..., that the use of such substances – **(ii) is necessary to the production or handling of agricultural product because of the unavailability of wholly natural substitute products; and (iii) is consistent with organic farming and handling;**" It is the "unavailability of wholly natural substitute products" that is being challenged.

The Technical Advisory Panel Report (TAPR) for silicon dioxide is available on the NOP website at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5068127&acct=nopgeninfo> is incorporated herein by reference.

In accordance with the Federal Register notice cited below, this Petition is hereby submitted as justification to remove Silicon Dioxide from the National List as an allowed synthetic non-agricultural substance.

Federal Register / Vol. 72, No. 11 / Thursday, January 18, 2007 / Rules and Regulations 2169

(12)B. Removal of a Synthetic from the National List, §§ 205.601, 205.603, 205.605(b)

1. Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
2. Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

1. Explain why the synthetic substance is no longer necessary:
  - a. Silicon Dioxide (a synthetic) has been a necessary ingredient in the food industry, since long before the establishment of the OFPA. At the time the Rule was adopted, there were no known "wholly natural substitute products"; therefore, Silicon Dioxide was appropriately given an exemption and placed on the National List as an approved synthetic.

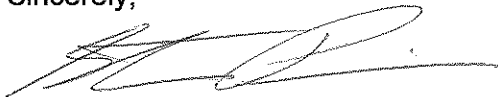
- b. In January 2007, RIBUS, Inc. of St Louis, MO commercially introduced a rice-based certified organic alternative to Silicon Dioxide.
- c. In May of 2007, during the public comment period of the Sunset Review for Silicon Dioxide, RIBUS provided written notification to the USDA of the commercial introduction and commercial availability of a rice-based certified organic alternative to Silicon Dioxide.
- d. Since 2007 RIBUS has produced tonnage quantities of this certified rice-based alternative to fill all orders. It is being sold domestically and internationally (of sufficient quantity and proper quality) for the uses cited in the TAPR for Silicon Dioxide.
- e. Therefore, one can conclude that in these application areas, Silicon Dioxide is no longer necessary in or on processed products labeled as "organic" or "made with organic" products.

2. Describe any non-synthetic alternative...

- a. A rice-based alternative (produced by RIBUS, Inc. of St Louis, MO) is produced from ground organic rice hulls. Rice hulls contain a high concentration of amorphous silica, the same active ingredient in silicon dioxide. RIBUS has developed an organically certified method to produce this natural/organic alternative to silicon dioxide.
- b. This rice-based alternative provides the same functionality as silicon dioxide in the above reference applications.
- c. This rice-based alternative is certified organic by Oregon Tilth and is accepted as organic by Certisys in the EU.

I trust that you will find this in compliance with the requirements of submitting a Petition. Should you have any questions or need additional information, we are prepared to reply promptly.

Sincerely,



Steve Peirce  
President

Attachments:

Product Specification Sheet

Cc: NOSB  
Oregon Tilth



## Product Specifications

<b>Product Analysis:*</b>	<u>Natural Nu-FLOW®</u>	<u>Organic Nu-FLOW®</u>
Protein	1.5% - 5%	1.5% - 5%
Fat	0.7% - 1.5%	0.7% - 1.5%
Carbohydrate	60% - 76%	60% - 76%
Ash	14% - 23%	14% - 23%
Dietary Fiber	55% - 72%	55% - 72%
Moisture	<4%	<4%

\*\* Product is natural and variations will occur.

**Description:** Concentrate of silica from rice, light tan in color, used to replace Silicone Dioxide (a synthetic) as an anti-caking agent.

### **Typical Use Rates:**

Anti-Caking Agent	1:1 replacer for SiO <sub>2</sub>
Pelletizing / Tableting	1:1 replacer for SiO <sub>2</sub>
Spray Drying	1:1 replacer for SiO <sub>2</sub>
Anti-Foaming	Determined by processor's needs

### **Benefits:**

- Eliminate a Synthetic
- Clean-up Labels
- No Maximum Use Rate
- Reduce Impact on Color
- Certified Organic

### **Particle Size Options:**

Nu-FLOW: < 70 micron

**Label:** "Rice Concentrate" or "Rice Hull Concentrate"

**Packaging:** 45 lbs bag in a box/27 boxes per pallet = 1,215 lbs

**Storage:** Store at <90° F (32 Celsius) and >32° F (0 Celsius)

**Shelf Life:** 2 years

### **Certifications:**

- Certified Organic – Oregon Tilth / EU
- Kosher Parve – OU
- GRAS - Self Affirmation

©2007 RIBUS, Inc., Nu-FLOW® is a trademark of RIBUS, Inc. This product is patent pending. Made in the USA

JUL 30 2010

**Item A**

This is a petition to **remove** from the National List, at §205.605(b), **Silicon Dioxide**, a synthetic non-agricultural (non-organic) substance currently allowed in or on processed products labeled as "Organic" or "Made with Organic (specified ingredients)."

**Item B**

**1. The common names of the substance (*being petitioned for removal*):** Silicon Dioxide, Silica Aerogel, Colloidal Silica. All are identified chemically as silicon dioxide, SiO<sub>2</sub>.

**2. The petitioner (*for the removal of the synthetic*) and the producer of the organic alternative:**

RIBUS, Inc.  
8000 Maryland Ave, #460  
St Louis, MO 63105  
Contact person – Steve Peirce, President  
Telephone: 314-727-4287  
Email address: steve@ribus.com

**3. The current use of the substance (*being petitioned for removal*):**

According to the TAP Reviews of Silicon Dioxide (September 1996) and Colloidal Silica (October 1995), attached as Appendices 1 and 2, silicon dioxide is used as an anti-caking agent, defoaming agent, carrier, conditioning agent, and chillproofing agent in malt beverages, and colloidal silica is used as an anti-caking agent, defoaming agent, carrier, and conditioning agent.

**4. The handling activities for which the substance (*being petitioned for removal*) is used and its mode of action:**

According to 21 CFR 172.480, silicon dioxide is used in food as an anti-caking agent in only those foods in which the additive has been demonstrated to have an anti-caking effect and in an amount not in excess of that reasonably required to produce its intended effect; as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing; and as an adsorbent for dl-a-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use.

According to 21 CFR 182.1711, silica aerogel is used as a component of an anti-foaming agent in accordance with good manufacturing practice.

Flow conditioners and anti-caking agents are finely-divided solids that are added to a host powder to improve its flowability and/or inhibit its tendency to cake.

**5. The source of the substance (*being petitioned for removal*) and a detailed description of its manufacturing or processing procedures:**

According to 21 CFR 172.480(a), the food additive silicon dioxide is manufactured by vapor phase hydrolysis or by other means.

According to 21 CFR 182.1711, silica aerogel is finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

U.S. Patent 3,872,217 (1975) describes a vapor phase hydrolysis process for forming substantially spherical, silica-containing hydrogels, by feeding a dilute mineral acid to the upstream end of a continuous-flow mixing zone; adding sodium or potassium silicate to said dilute acid at various points distributed along the downstream path of said dilute acid at temperatures of from 5°C to 45°C, the dilute acid and the silicate being fed to the mixing zone in such an amount that the silica hydrosol formed in the mixing zone reaches a pH of from 5 to 10; and spraying said silica hydrosol into a gaseous medium to form droplets of hydrosol which solidify to a spherical silica hydrogel while freely falling.

#### **6. A summary of previous reviews of the substance (*being petitioned for removal*).**

The TAP Reviews of Silicon Dioxide (September 1996) and Colloidal Silica (October 1995) are attached as Appendices 1 and 2.

#### **7. EPA, FDA, and State regulatory authority registrations (*of the substance being petitioned for removal*).**

The primary regulatory citation for the food additive silicon dioxide is 21 CFR 172.480(a). The primary regulatory citation for the food additive silica aerogel is 21 CFR 182.1711. These two sections of the regulations are attached as Appendices 3 and 4, respectively.

#### **8. Chemical Abstract Service (CAS) numbers (*of the substance being petitioned for removal*).**

Silicon dioxide is the chemical name for sand as well as for the very fine particles sold as anti-caking agents. The following table shows the multiple CAS numbers found in a search for "silicon dioxide."

Name	CAS Number
Silicon dioxide	60676-86-0
Silicon dioxide	14808-60-7
Silicon dioxide	7631-86-9
Fumed silicon dioxide	112945-52-5
Colloidal silicon dioxide	112945-52-5
Silicon dioxide fume	69012-64-2
Colloidal silicon dioxide	7631-86-9
Crystalline silicon dioxide, tridymite	15468-32-3
Crystalline silicon dioxide	14808-60-7
Crystalline silicon dioxide, cristobalite	14464-46-1

A search for "silica" yields a similar plethora of CAS numbers, most of which are the same as those found for silicon dioxide.

Name	CAS Number
Silica	14808-60-7
Silica	7631-86-9
Silica amorphous, diatomaceous earth (>1% crystalline silica)	61790-53-2
Silica flour (powdered crystalline silica)	14808-60-7
Synthetic amorphous silica, fumed	112945-52-5
Silica, amorphous, fumed, crystal-free	112945-52-5
Silica, amorphous fumed	112945-52-5
Silica, amorphous	112945-52-5
Silica (non Silicon dioxide -specific name)	112945-52-5
Pyrogenic silica	112945-52-5
Pyrogenic colloidal silica	112945-52-5

**9. Physical properties and chemical mode of action (*of the substance being petitioned for removal*).**

**(a) chemical interactions with other substances:**

Silicon dioxide is relatively inert chemically. Forms of silicon dioxide found in nature are sand, diatomaceous earth, and a natural component of rice hulls.

**(b) toxicity and environmental persistence:**

Silicon dioxide of small particle size may cause irritation and adverse health effects on the skin (eyes) and lungs (silicosis). See the MSDS for silicon dioxide in the TAP Reviews (Appendices 1 and 2). Silicosis is a chronic disease of the lungs that is caused by the inhalation of silica dust over long period of time.

Silicon dioxide persists in the environment: consider the common soil component sand. However, adverse effects of silicon dioxide are related to very small particle size, and primarily airborne silicon dioxide.

**(c) environmental impacts from its use or manufacture:**

Silicon dioxide of small particle size may cause irritation and adverse health effects on the skin (eyes) and lungs (silicosis). See the MSDS for silicon dioxide in the TAP Reviews (Appendices 1 and 2).

**(d) effects on human health:**

Silicon dioxide of small particle size may cause irritation and adverse health effects on the skin (eyes) and lungs (silicosis). Silicosis is a chronic disease of the lungs that is caused by the inhalation of silica dust over long period of time.

**(e) effects on soil organisms, crops, or livestock:**

Silicon dioxide persists in the soil. Sand is silicon dioxide and a common soil component. The adverse effects of silicon dioxide for humans and livestock would be related to very small particle size, particularly airborne silicon dioxide.

**10. Safety information (*on the substance being petitioned for removal*).**

See the MSDS for silicon dioxide in the TAP Reviews (Appendices 1 and 2).

**11. Research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions (on the substance being petitioned for removal).**

See the TAP Reviews (Appendices 1 and 2) for reviews of silicon dioxide as a food additive.

Several years ago, the Food and Drug Administration contracted with the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology as part of its comprehensive review of GRAS and prior sanctioned food ingredients. To aid in that review, LSRO established the Select Committee on GRAS Substances (SCOGS). SCOGS published a 1979 report on silicates (SCOGS Report No. 61, *Evaluation of the Health Aspects of Certain Silicates as Food Ingredients*, 1979).

UNEP Chemicals published a report in 2005 on certain forms of silicon dioxide, summarizing the toxicological and other data. This 254-page report is available on the internet at <http://www.chem.unep.ch/irptc/sids/oecd/sids/Silicates.pdf>.

As a restatement of Item B-3 above, Appendices 1 and 2, the TAP Reviews discuss many different uses of the SiO<sub>2</sub> for which it was approved. The proposed rice concentrate has been produced and sold in commercial quantities (domestically and internationally) to organic and natural food / feed producers for many of the exact same uses as SiO<sub>2</sub>. Listed below is comparative data and the enhancements made to the ingredient (both certified organic and natural) since its introduction in 2007.

Table 1. Use Rates of Organic Rice Concentrate vs. SiO<sub>2</sub>

	<u>2007-2008*</u>	<u>2009-Present*</u>
Spice Blends	1:1 or 1.2:1	1:1
Dry Beverages	Did not work	1:1
Dried Fruit	Did not work	1:1
Tablets	1.1 or 1.2:1	1:1
Sauce Mixes	1.1 or 1.2:1	1:1
Livestock Supplements	1.1 or 1.2:1	1:1
Flavor Carrier (oil & water)	1.2:1	0.8:1 or 1:1

\*Ratios are expressed as rice concentrate : SiO<sub>2</sub>

**Product Generation 1:**

In 2007, when RIBUS introduced a rice-hull-based certified organic alternative to Silicon Dioxide to the market, our product specification stated <10% moisture. Initial trials showed reasonable performance in spices, sauce mixes and livestock supplements, but unsatisfactory results in dry beverage mixes and dried fruit, as table 1 shows. Use rates in successful applications were 1:1 or 1.2:1 versus Silicon Dioxide, because of the 7-8% moisture in the products.

**Product Generation 2:**

In 2009 new equipment was installed that produced an organic ingredient with 2-3% moisture. Our specifications were re-written to require <4% moisture. We immediately saw the results shown in table 1. The dryness of the ingredient allowed it to be used in hydroscopic systems such as dried fruit and dry beverage mixes.

**Product Generation 3:**

Because of the demand for the product from the “non-organic” food sector, RIBUS has developed a “natural” non-organic form of the rice-hull based product to be used in non-organic foods. There were actually some natural producers that were buying the organic ingredient to be used in non-certified organic / natural spices to sustain a claim of “no synthetic ingredients.”

I trust that this comparative data shows the enhancements that have been made to the rice-hull based certified organic alternative to Silicon Dioxide, the interest level in the market place (both organic and natural), as well as some use limitations when the higher moisture product was first introduced. While the synthetic material SiO<sub>2</sub> has been used widely in the food industry for many years, the above referenced areas are our areas of focus and commercially demonstrated efficacy.

## **12. Justification for Removal of Silicon Dioxide from the National List.**

Silicon dioxide is relatively inert chemically. Forms of silicon dioxide found in nature are sand, diatomaceous earth, and a natural component of rice hulls.

According to the OFPA, “The National List may provide for use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if . . . the Secretary determines, . . . that the use of such substances . . . is necessary to the production or handling of agricultural product because of the unavailability of wholly natural substitute products . . .”

A wholly natural and certified organic substitute product IS now available.

As indicated above in 9(a), rice hulls are rich in silica. It has been known for over 70 years that silicon is beneficial in the normal growth of rice. The rice plant accumulates silica in the rice hull.

The petitioner RIBUS, Inc. of St Louis, MO, commercially introduced a rice-hull-based certified organic alternative to Silicon Dioxide in January 2007. In May of 2007, during the public comment period of the Sunset Review for Silicon Dioxide, RIBUS provided written notification to the USDA of the commercial introduction and commercial availability of a rice-hull based certified organic alternative to Silicon Dioxide. Today this certified rice-based alternative is being sold domestically and internationally (of sufficient quantity and proper quality) for the uses cited in the TAP Reports for Silicon Dioxide and Colloidal Silica to manufacturers and producers of:

- Organic & Natural Spices
- Organic & Natural Tablets
- Organic Dried Fruit
- Dry Beverage Powder
- Dry Sauce Mixes
- Organic Livestock Supplements

The consequent conclusion is that Silicon Dioxide, a synthetic non-agricultural (non-organic) substance, is no longer necessary in or on processed products labeled as “organic” or “made with organic (ingredients)”, due to the commercial availability of a certified organic alternative.

Nothing in the present Petition is considered to CBI (Confidential Business Information).



**NOSB NATIONAL LIST  
FILE CHECKLIST**

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**PROCESSING**

~~Exhibit~~

Appendix 1

**MATERIAL NAME:** # 9 Silicon dioxide



**NOSB Database Form**



**References**



**MSDS (or equivalent)**



**FASP (FDA)**



**TAP Reviews from:** Rich Theuer, Joe  
Montecalvo, James  
Johnson, William Zimmer,  
Walter Jeffery

**NOSB/NATIONAL LIST  
COMMENT FORM  
PROCESSING**

04-27-10 A08:11 IN

**Material Name: #9 Silicon dioxide**

*Please use this page to write down comments, questions, and your anticipated vote(s).*

**COMMENTS/QUESTIONS:**

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1. In my opinion, this material is:  
\_\_\_\_\_ Synthetic \_\_\_\_\_ Non-synthetic.

2. Should this material be allowed in an "organic food" (95% or higher organic ingredients)? \_\_\_\_\_ Yes \_\_\_\_\_ No  
***(IF NO, PROCEED TO QUESTION 3.)***

3. Should this substance be allowed in a "food made with organic ingredients" (50% or higher organic ingredients)? \_\_\_\_\_ Yes \_\_\_\_\_ No

04-27-10 A08:11 IN

# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Silicon Dioxide

Reviewer Name: R C Thewer RECEIVED 08 05 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

SYNTHETIC

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed  Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

in accordance with GMP's

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

ADEQUATE

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material?  Yes;  No

Signature Richard C Thewer Date 8/5/96

USDA/TAP REVIEWER  
COMMENT FORM

Mailing date: 1 Jul 1996.

Due date: 5 Aug 1996

04 27-10A08:13 RCVD

Name of Materials Silicon Dioxide  
Reviewer Name: Richard C. Theuer

**SYNTHETIC** Silicon dioxide is produced synthetically as described in the NOSB Materials Database form.

COMMENTS RE SECTION 2119(m) CRITERIA:

1. The amount of silicon dioxide used in foods is limited by good manufacturing practices. The primary use that I am aware of is as a carrier, anticaking agent and defoaming agent. Small amounts are effective, and prevent waste (from caking) and overusage (by diluting and thus making it easier to add the smallest effective amount of other additives (nutrients, for example).
2. Silicon dioxide is found in nature as sand, so the impact of silicon dioxide which finds its way into the environment is benign.

The following synthetic substance should be allowed as an ingredient in organic foods. It should be added to the National List of synthetic substances allowed for use as ingredients or processing aids in Organic Food:

silicon dioxide

5 August 1996

# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Silicon Dioxide

Reviewer Name: JAMES A. JOHNSON RECEIVED JUL 3 0 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed  Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List  
*been on lack of info*

Are there any use restrictions or limitations that should be placed on this material on the National List?

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

Any additional comments? (attachments welcomed)

*Could not find additional info on this material*

Do you have a commercial interest in this material?  Yes;  No

Signature James A. Johnson Date 7/29/96

Please address the 7 criteria in the Organic Foods Production Act:  
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

N/A

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

unknown

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

(b)

- (4) the effect of the substance on human health;

Unknown

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

unknown

- (6) the alternatives to using the substance in terms of practices or other available materials; and

Unknown to reviewer

- (7) its compatibility with a system of sustainable agriculture.

Even though EU and Codex may have found this material safe at certain doses, it is not clear as the answer to such agents.

# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Silicon Dioxide

Reviewer Name: JOE Montecalvo RECEIVED AUG 0 5 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

can be either Synthetic or non synthetic

If synthetic, how is the material made? (please answer here if our database form is blank) - See DATA BASE

This material should be added to the National List as:

Synthetic Allowed <sup>ie ARC SiO2</sup>  Prohibited Natural <sup>ie manufactured by other chemical means</sup>  
or,  Non-synthetic (Allowed as an ingredient in organic food)  
 Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

<sup>ie SiO2 is manufactured from high purity sand that is vaporized at 3000°C electric ARC, this is called ARC SiO2 and is physically separated from other materials in the sand. there is no chemical reaction, therefore ie SiO2 if made this way, I would suggest</sup>  
Please comment on the accuracy of the information in the file: <sup>ie Synthetic Allowed</sup>  
Partial info - see pp 842-843 of the Chemical Dictionary, 7th ed pub by VAN Nostrand Reinhold.

Any additional comments? (attachments welcomed)

It seems that fumed SiO2 can be manufactured in different ways

Do you have a commercial interest in this material?  Yes;  No

Signature DR Joe Montecalvo Date 7/26/96

Please address the 7 criteria in the Organic Foods Production Act:  
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

NONE

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

NONE

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

NONE

- (4) the effect of the substance on human health;

Prolonged inhalation of the dust ( $SiO_2$ ) can cause fibrosis of the lungs leading to a medical condition known as Silicosis. Hence, use of this compound for long periods of time, a respiratory protective device should be used.

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

NONE

- (6) the alternatives to using the substance in terms of practices or other available materials; and - Magnesium carbonate may serve as an alternative in anti-caking functions.

- (7) its compatibility with a system of sustainable agriculture.

borderline; should have application only as a anti-caking ingredient in food processing and for de-coloring (ie in Jam/Jelly manufacturing)



# TAP REVIEWER COMMENT FORM for USDA/NOSB

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This file is due back to us by: Aug. 5, 1996

Name of Material: Silicon Dioxide

Reviewer Name: WALTER JEFFERY RECEIVED JUL 29 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed  Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

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

Any additional comments? (attachments welcomed)

*one of the least offensive anticaking agents*

Do you have a commercial interest in this material?  Yes;  No

Signature Walter Jeffery

Date 7/24/96

Please address the 7 criteria in the Organic Foods Production Act:  
(comment in those areas you feel are applicable)

- 1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

*little or no potential for detrimental chemical interactions*

- 2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

*non toxic*

- 3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

*very little to none*

- 4) the effect of the substance on human health;

*no effect*

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

*no effect*

- (6) the alternatives to using the substance in terms of practices or other available materials; and

*magnesium carbonate, other silica compounds*

- (7) its compatibility with a system of sustainable agriculture.

*not really a problem, there is more than enough naturally*

# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: Aug. 5, 1996

Name of Material: Silicon Dioxide

Reviewer Name: William A. Zimmer D.V.M. RECEIVED JUL 3 0 1996

Is this substance Synthetic or non-synthetic? Explain (if appropriate) Synthetic  
If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:  
 Synthetic Allowed  Prohibited Natural  
or,  Non-synthetic (Allowed as an ingredient in organic food)  
 Non-synthetic (Allowed as a processing aid for organic food)  
or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

Please comment on the accuracy of the information in the file:  
fairly complete, accurate

Any additional comments? (attachments welcomed)  
Uses - moisture scavenger, drying agent

Do you have a commercial interest in this material?  Yes;  No

Signature William A. Zimmer D.V.M. Date 7-8-96

Please address the 7 criteria in the Organic Foods Production Act:  
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

*none*

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

*none*

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

*none*

- (4) the effect of the substance on human health;

*Dust laden air should not be breathed in. Breathing apparatus should be used when working with concentrated silicon dioxide. Fineness of dust may cause silicosis of airway passages if excessive amounts are breathed in.*

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

*none*

- (6) the alternatives to using the substance in terms of practices or other available materials; and

- (7) its compatibility with a system of sustainable agriculture.

*Compatible*

# NOSB Materials Database

1

## Identification

04-27-10A08:14 RCVD

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<sub>2</sub>**  
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 alkalis.**  
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)**  
Type of Use **Processing**

## Use/Action

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

Historical status

International status **Allowed by EU and Codex.**

# NOSB Materials Database

## OFPA Criteria

2

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

2119(m)5: agroecosystem biology

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, talc, starches, and modified carbohydrates. Varying the concentration of these additives can produce certain effects.

04-27-10A08:14 RCVD

# NOSB NATIONAL LIST FILE CHECKLIST

## PROCESSING

*Appendix # 2*

**MATERIAL NAME:** # 7 Colloidal Silica



**NOSB Database Form**



**References**



**MSDS (or equivalent)**



**FASP (FDA)**



**TAP Reviews from: Joe Montecalvo, Rich  
Theuer**

**NOSB/NATIONAL LIST  
COMMENT FORM  
PROCESSING**

04-27-10A08:14 RCVD

**Material Name: #7 Colloidal Silica**

*Please use this page to write down comments, questions, and your anticipated vote(s).*

**COMMENTS/QUESTIONS:**

---

1. In my opinion, this material is:  
 Synthetic  Non-synthetic.

2. Should this material be allowed in an "organic food" (95% or higher organic ingredients)?  Yes  No  
**(IF NO, PROCEED TO QUESTION 3.)**

3. Should this substance be allowed in a "food made with organic ingredients" (50% or higher organic ingredients)?  Yes  No



# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: August 8

Name of Material: Colloidal Silica

Reviewer Name: \_\_\_\_\_

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

Synthetic

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

Synthetic Allowed                       Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

only for specific uses

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

Any additional comments? (attachments welcomed) none

Do you have a commercial interest in this material?  Yes;  No

Signature [Handwritten Signature]

Date 7/30/95

**Please address the 7 criteria in the Organic Foods Production Act:  
(comment in those areas you feel are applicable)**

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;**

*none*

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;**

*none*

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;**

*none*

- (4) the effect of the substance on human health;**

*none*

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;**

*none*

- (6) the alternatives to using the substance in terms of practices or other available materials; and**

*none*

- (7) its compatibility with a system of sustainable agriculture.**

*O.K.*

# TAP REVIEWER COMMENT FORM for USDA/NOSB

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. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: August 8

Name of Material: Colloidal Silica

Reviewer Name: R. Theuer

Is this substance Synthetic or non-synthetic? Explain (if appropriate)

SYNTHETIC

If synthetic, how is the material made? (please answer here if our database form is blank)



This material should be added to the National List as:

Synthetic Allowed       Prohibited Natural

or,  Non-synthetic (Allowed as an ingredient in organic food)

Non-synthetic (Allowed as a processing aid for organic food)

or,  this material should not be on the National List

Are there any use restrictions or limitations that should be placed on this material on the National List?

CURRENTLY ALLOWED USES

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

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material?  Yes;  No

Signature R. Theuer

Date 8/28/51

**Please address the 7 criteria in the Organic Foods Production Act:**  
(comment in those areas you feel are applicable)

- (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

NO ISSUE

- (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

NO ISSUE

- (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

NO ISSUE

- (4) the effect of the substance on human health;

DUST IS A PROBLEM

LOW USAGE LEVEL IN FOODS ARE SAFE

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

NO ISSUE

- (6) the alternatives to using the substance in terms of practices or other available materials; and

OTHER MINERALS (TALC) CAN BE WORSE

- (7) its compatibility with a system of sustainable agriculture.

OK.

# NOSB Materials Database

1

## Identification

04-27-10A08:14 RCVD

<b>Common Name</b>	<b>Colloidal Silica</b>	<b>Chemical Name</b>	
<b>Other Names</b>	Synthetic Amorphous Silica, Fumed Silica		
<b>Code #: CAS</b>	1343-98-2	<b>Code #: Other</b>	NIOSH NO.: VV8850000
<b>N. L. Category</b>	Non-agricultural	<b>MSDS</b>	<input checked="" type="radio"/> yes <input type="radio"/> no

## Chemistry

<b>Family</b>	
<b>Composition</b>	SiO <sub>2</sub> . Amorphous substance that shows a noncrystalline pattern when examined by X-ray diffraction.
<b>Properties</b>	White fluffy, non-gritty powder of very fine particle size. Hygroscopic. Negligible solubility in water or organic solvents, but soluble in hydrofluoric acid and in hot concentrated solutions of alkalis; specific gravity 2.10.
<b>How Made</b>	Produced synthetically by a vapor-phase hydrolysis process, which yields the (anhydrous) fumed (or colloidal) silica. Wet-process yields silica gel which is hydrated.

## Use/Action

<b>Type of Use</b>	Processing
<b>Specific Use(s)</b>	Anti-caking agent, defoaming agent, carrier, conditioning agent.
<b>Action</b>	
<b>Combinations</b>	

## Status

<b>OFPA</b>	
<b>N. L. Restriction</b>	
<b>EPA, FDA, etc</b>	FDA-GRAS
<b>Directions</b>	
<b>Safety Guidelines</b>	
<b>State Differences</b>	
<b>Historical status</b>	
<b>International status</b>	

# NOSB Materials Database

2

## 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

2119(m)5: agroecosystem biology      Not Applicable  
2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

## References

AU: Krishna,-A.G.G.

TI: A method for bleaching rice bran oil with silica gel.

SO: J-Am-Oil-Chem-Soc. Champaign, Ill. : The Society. Dec 1992. v. 69 (12) p. 1257-1259.

CN: DNAL 307.8-J82

AU: Rao,-Gangadhar-Vemunganti.; Pfof,-Harry-B., 1919-

TI: Regeneration capacity of silica gel for grain drying.

SO: Manhattan, Kan.: Kansas State Univ., Food & Feed Grain Institute, 1974. ii, 32 p.

CN: DNAL SB188.G7-no.7

-----  
**MSDS for SILICA GEL**  
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04-27-10A08:14 RCVD

-----  
**1 - PRODUCT IDENTIFICATION**  
-----

PRODUCT NAME: SILICA GEL  
FORMULA: FORMULA WT: .00  
CAS NO.: 1343-98-2 NIOSH/RTECS NO.: VV8850000  
COMMON SYNONYMS: AMORPHOUS SILICON DIOXIDE; SILICIC ACID  
PRODUCT CODES: 7290,3406,3404,3405,5111  
EFFECTIVE: 06/09/86 REVISION #02

PRECAUTIONARY LABELLING

BAKER SAF-T-DATA(TM) SYSTEM

HEALTH - 1 SLIGHT  
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 MAY BE HARMFUL IF INHALED  
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**  
-----

COMPONENT	%	CAS NO.
SILICA GEL	90-100	01343-98-2

-----  
**3 - PHYSICAL DATA**  
-----

BOILING POINT: 2230 C ( 4046 F) VAPOR PRESSURE(MM HG): N/A  
MELTING POINT: N/A VAPOR DENSITY(AIR=1): N/A  
SPECIFIC GRAVITY: 2.10 EVAPORATION RATE: N/A  
(H<sub>2</sub>O=1) (BUTYL ACETATE=1)  
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

SOLUBILITY(H<sub>2</sub>O): NEGLIGIBLE (LESS THAN 0.1 %) % VOLATILES BY VOLUME: N/A  
APPEARANCE & ODOR: ODORLESS, WHITE, GRANULAR POWDER (AMORPHOUS).

-----  
**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.  
SPECIAL FIRE-FIGHTING PROCEDURES:  
FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED  
BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.

-----  
**5 - HEALTH HAZARD DATA**  
-----

THRESHOLD LIMIT VALUE (TLV/TWA): 10 MG/M3 ( PPM)

CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO  
EFFECTS OF OVEREXPOSURE

PROLONGED CONTACT MAY CAUSE SKIN IRRITATION.  
DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.

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: MOISTURE

INCOMPATIBLES: HYDROGEN FLUORIDE

---

#### 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: STABLE USE GENERAL OR LOCAL EXHAUST VENTILATION TO MEET CUR  
TLV REQUIREMENTS.

CONDITIONS TO AVOID: MOISTURE

RESPIRATORY PROTECTION: RESPIRATORY PROTECTION REQUIRED IF AIRBORNE

INCOMPATIBLES: CONCENTRATION EXCEEDS TLV. AT CONCENTRATIONS  
ABOVE 10 MG/M<sup>3</sup>, A DUST/MIST RESPIRATOR IS RECOMMENDED.

EYE/SKIN PROTECTION: --- SAFETY GLASSES WITH SIDESHIELDS, PROPER GLOVES ARE ---  
RECOMMENDED.

---

#### 9 - STORAGE AND HANDLING PRECAUTIONS

---

DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL  
SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

SPECIAL PRECAUTIONS

KEEP CONTAINER TIGHTLY CLOSED. SUITABLE FOR GENERAL 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)



04-27-10A08:15 RCVD

**Food and Drug Administration, HHS****§ 172.490**

(3) Labels of manufactured foods containing the additive shall bear, in the ingredient statement, the name of the additive, "whole fish protein concentrate" in the proper order of decreasing predominance in the finished food.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

**§ 172.395 Xylitol.**

Xylitol may be safely used in foods for special dietary uses, provided the amount used is not greater than that required to produce its intended effect.

**§ 172.399 Zinc methionine sulfate.**

Zinc methionine sulfate, CAS Reg. No. 56329-42-1, may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the reaction between equimolar amounts of zinc sulfate and DL-methionine in purified water.

(b) The additive meets the following specifications:

Zinc content—19 to 22 percent.

C<sub>5</sub>H<sub>11</sub>NO<sub>2</sub>S "DL-methionine"—46 to 50 percent.

Cadmium—not more than 0.05 part per million.

(c) The additive is used in tablet form as a source of dietary zinc.

[46 FR 58297, Dec. 1, 1981]

**Subpart E—Anticaking Agents****§ 172.410 Calcium silicate.**

Calcium silicate, including synthetic calcium silicate, may be safely used in food in accordance with the following prescribed conditions:

(a) It is used as an anticaking agent in food in an amount not in excess of that reasonably required to produce its intended effect.

(b) It will not exceed 2 percent by weight of the food, except that it may be present up to 5 percent by weight of baking powder.

**§ 172.430 Iron ammonium citrate.**

Iron ammonium citrate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used, or intended for use as an anticaking agent in salt for human consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

**§ 172.480 Silicon dioxide.**

The food additive silicon dioxide may be safely used in food in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used as an anticaking agent, subject to the following conditions:

(1) It is used in only those foods in which the additive has been demonstrated to have an anticaking effect.

(2) It is used in an amount not in excess of that reasonably required to produce its intended effect.

(3) [Reserved]

(4) It is used in an amount not to exceed 2 percent by weight of the food.

(c) It is used or intended for use as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing.

(d) It is used or intended for use as an adsorbent for *dl*- $\alpha$ -tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use, in an amount not greater than that required to accomplish the intended physical or technical effect.

**§ 172.490 Yellow prussiate of soda.**

(a) The food additive yellow prussiate of soda (sodium ferrocyanide decahydrate; Na<sub>4</sub>Fe(CN)<sub>6</sub>·10H<sub>2</sub>O) contains a minimum of 99 percent by weight of sodium ferrocyanide decahydrate.

(b) The additive is used or intended for use as an anticaking agent in salt and as an adjuvant in the production of dendritic crystals of salt in an amount

**§ 182.1180**

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1180 Caffeine.**

- (a) *Product.* Caffeine.  
 (b) *Tolerance.* 0.02 percent.  
 (c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

**§ 182.1217 Calcium phosphate.**

- (a) *Product.* Calcium phosphate (mono-, di-, and tribasic).  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1235 Caramel.**

- (a) *Product.* Caramel.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1320 Glycerin.**

- (a) *Product.* Glycerin.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1480 Methylcellulose.**

- (a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1500 Monoammonium glutamate.**

- (a) *Product.* Monoammonium glutamate.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1516 Monopotassium glutamate.**

- (a) *Product.* Monopotassium glutamate.

**21 CFR Ch. I (4-1-09 Edition)**

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1711 Silica aerogel.**

- (a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.  
 (b) [Reserved]  
 (c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of an anti-foaming agent in accordance with good manufacturing practice.

**§ 182.1745 Sodium carboxymethylcellulose.**

- (a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25 °C.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1748 Sodium caseinate.**

- (a) *Product.* Sodium caseinate.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1778 Sodium phosphate.**

- (a) *Product.* Sodium phosphate (mono-, di-, and tribasic).  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

**§ 182.1781 Sodium aluminum phosphate.**

- (a) *Product.* Sodium aluminum phosphate.  
 (b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.



# Oregon Tilth Certified Organic

260 SW Madison Ave. Ste, 106, Corvallis, OR 97333  
(503) 378-0690, fax (541) 753-4924

## Certification Acknowledgement

This is to certify that

**RIBUS, Inc.**  
**8000 Maryland Avenue #460**  
**Saint Louis, MO 63105**  
**United States of America**

is certified organic by Oregon Tilth Certified Organic (OTCO)

### **Class OM - Organic Marketer**

Certification Number MO-OTCO-CO-09-0119

The certified operation has complied with the Organic Foods Production Act of 1990 and the applicable organic production and handling standards established by the USDA National Organic Program under 7 CFR Part 205.

The organic products are:

**100% Organic Products:**  
Nu-Flac Tea Cut, Nu-Flow 70R.

#### **Organic Products:**

Nu-Bake Rice Bran Extract, Nu-Rice Rice Bran Extract, Oryza-Mul Rice Bran Extract.

The certified operation has been inspected annually by an agent of the OTCO program to verify to the best of our knowledge the standards have been met. Certification remains valid until surrendered, suspended, or revoked.

**Certified by OTCO since:** 4/2/2009  
**NOP effective date:** 4/2/2009

*Kristy Kohl*  
signed and dated MAY 14, 2010  
Certification Director



# Oregon Tilth Certified Organic

260 SW Madison Ave, Ste 106, Corvallis OR. 97333 USA phone (503) 378-0690, fax (541) 753-4923  
email: [organic@tilth.org](mailto:organic@tilth.org) website: [www.tilth.org](http://www.tilth.org)

## Declaration of Compliance with EC 834/2007\*

**\*Assessed via ACB EU Equivalency Standard**

Oregon Tilth Certified Organic (OTCO) hereby guarantees that the inspection system and precautionary measures required by EU Council Regulation (EC) 834/2007 and its amendments are permanently and effectively applied to the certified operation identified in this declaration of compliance.

The certified operation has been evaluated by an agent of the OTCO program to verify to the best of our knowledge that the organic production standards established in EC 834/2007 have been met. Any infringements of said regulation may result in penalties according to OTCO rules. Evaluation is assessed via the ACB EU Equivalency Standard which has been evaluated and deemed equivalent to EC 834/07.

**Certified Operation:** RIBUS, Inc.  
8000 Maryland Avenue #460  
Saint Louis, MO 63105  
United States of America

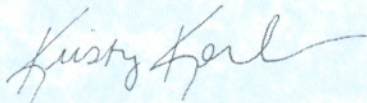
**Class of Operation:** OM

**Certificate Number:** MO-OTCO-CO-09-0119

**Certified Products:** Organic Products: Nu-Flac Tea Cut, Nu-Flow 70R, Nu-Bake Rice Bran Extract, Nu-Rice Rice Bran Extract, Oryza-Mul Rice Bran Extract.

**Effective Date:** 4/2/2010 to 4/1/2011

Name and signature of authorized person:



Kristy Korb, Certification Director



Stamp of certification authority



Congress of the United States

Washington, DC 20515

November 1, 2007

Charles F. Conner  
Acting Secretary of Agriculture  
United States Department of Agriculture  
1400 Independence Avenue SW  
Washington, DC 20250

04-27-10A08:16 RCVD

Dear Mr. Secretary:

We are writing to bring to your attention an issue relating to the recently published *National List of Allowed and Prohibited Substances*.

As you are aware, the Organic Foods Production Act of 1990 requires the Secretary of Agriculture to establish a *National List of Allowed and Prohibited Substances* which identifies synthetic substances that may be used, and the non-synthetic substances that cannot be used, in organic production and handling operations.

Missouri-based RIBUS, Inc. produces a wholly natural alternative to silicon dioxide from rice hulls. This substitute product made by RIBUS is certified organic by Quality Assurance International and is commercially available according to RIBUS. RIBUS notified USDA of the availability of the alternative to silicon dioxide during the most recent public comment period.

Please review the information provided by RIBUS during the public comment period and determine whether leaving silicon dioxide on the *National List of Allowed and Prohibited Substances* is in conflict with Title VII of the Organic Foods Production Act, which states that the *National List* may provide for the use of non-organic substances only if the Secretary of Agriculture, Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency determine that the use of such substances is necessary to the production or handling of agricultural products because of the unavailability of a wholly natural substitute product.

Thank you for your attention to this matter, and we look forward to your response.

Sincerely,



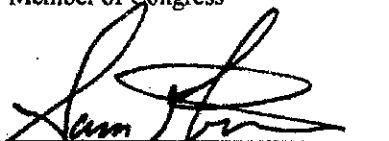
CHRISTOPHER S. BOND  
United States Senator



RUSS CARNAHAN  
Member of Congress



JO ANN EMERSON  
Member of Congress



SAM GRAVES  
Member of Congress



04-27-10A08:15 RCVD

May 04, 2007

Docket # TM-04-07

Ms. Toni Strother  
Agricultural Marketing Specialist  
National Organic Program  
USAD-AMS-TMP-NOP  
1400 Independence Ave SW  
Room 4008-So., Ag Stop 0268  
Washington, DC 20250

The purpose of this letter is to provide written comments addressing the "published recommendations in the proposed rule pertain to the continued exemption (use) and prohibition of 169 substances in organic production and handling." (Federal Register Vol. 72, No. 43, Tuesday, March 6, 2007)".

- Topic and Section:
  - The topic is the proposed exemption allowing the use of Silicon Dioxide (synthetic) in organic foods.
  - Section 205.605 Nonagricultural (Nonorganic) Substances Allowed as Ingredients In or On Processed Products Labeled As "Organic" or "Made With Organic (Specified Ingredients or Food Groups(s))"
    - (b) Synthetics allowed:
      - 35. Silicon Dioxide

It is my desire to bring new information to the NOP, thereby making a statement against the exemption being proposed for Silicon Dioxide.

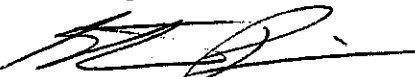
- Proposed Language
  - In light of the recent commercialization of a "certified organic" replacement for silicon dioxide, a re-review of the Sunset provision seems warranted and timely.
  - Intent: The identified synthetic (silicon dioxide) listed above should not be used in organic production unless the processor can prove they have tested "the organic alternative" and determined that it does not function or is not commercially available.
    - This is the same intent / language used historically for bleached lecithin and other new forms of organic ingredients.
- Articles of Reference
  - New Product Commercialization's / New Inventions
    - In August 2006, a Provisional Patent was filed with the US Patent & Trademark Office. The actions were taken to secure domestic and international patent protection for this silicon dioxide replacer.

- Since this technology had not been publicly disclosed during the 60 day comment period beginning on June 17, 2005, it was impossible to provide comments prior to this time. It is understood that the majority of the comments “urged the current list to remain in tact as it currently exists”; however with new products entering the market, there is a need for the Sunset Review process to be conducted with full knowledge available.
- Commercial Availability
  - RIBUS has existing agreements in place with commercial suppliers, processors, warehouses and its management team to ensure “Commercial Availability”. Many of these providers have a multi-year relationship with our firm.
  - Nu-FLOW™ from RIBUS is commercially available and has been approved by 3+ companies (over the past 90 days) for commercial applications within the organic industry. At the time of this submission, testimonial letters or public disclosure of their ingredient formulation were not available.
- Product Literature / Application Information
  - Technical Literature / Exhibits
    - Attached are various exhibits of product literature and technical information on the product.
      - Organic Certificate (by QAI)
      - Product Specification Sheets
      - Product Application Literature

Based upon this information that “certified organic” ingredients do exist that effectively function as alternatives / replacements to the specific “synthetic”, silicon dioxide; it is my desire to see the above referenced exemption repealed (or disallowed).

Should the National Organic Program have any questions, it would be our pleasure to answer them.

Best Regards,



Steve Peirce  
President

attachments



## UNITED STATES PATENT AND TRADEMARK OFFICE

04-27-10A08:16 RCVD

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
60/835,062	08/02/2006		100	CHC 3994		3	

CONFIRMATION NO. 8062

2147  
 GRACE J FISHEL  
 2200 WEST PORT PLAZA DRIVE  
 SUITE 202  
 ST. LOUIS, MO 63146

## FILING RECEIPT



\*0C000000020064520\*

Date Mailed: 08/17/2006

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Neal A. Hammond, Cameron Park, CA;  
 J. Steve Peirce, St. Louis, MO;

## Power of Attorney:

Grace Fishel-25864

If Required, Foreign Filing License Granted: 08/16/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US60/835,062**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: Not applicable

Early-Publication Request: Not applicable

\*\* SMALL ENTITY \*\*

## Title

Biogenic silica from silica-containing plant material such as rice hulls



Certificate of Compliance

04-27-10A08:16

# Certified Organic



Number 104291-B

**Certified Entity**

Ribus, Inc.  
20 S. Central Ave.  
St. Louis, MO 63105  
USA

**Type of Operation**

Handler (Trader)

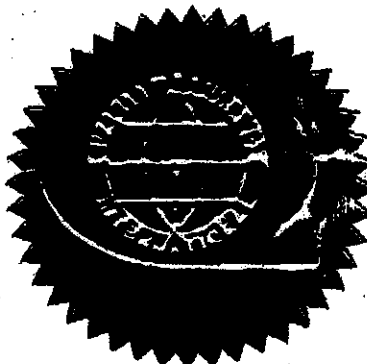
**Location Inspected**

Ribus, Inc.  
20 S. Central Ave., #106  
St. Louis, MO 63105  
USA

**Effective Date**

May 19, 2004

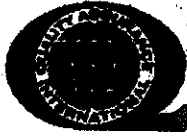
Quality Assurance International, upon providing this certification, states that it has received the Certified Entity's application, reviewed its records, inspected its fields and/or facilities; and has determined that the certified entity identified above is operating in accordance with the Organic Foods Production Act of 1990 and 7 CFR Part 205. In its acceptance of this certification, the certified entity warrants, that it is in, and will remain in, full compliance with the Terms and Conditions of the Certification Agent; and in accordance with general guidelines established by the USDA's National Organic Program.



Certification valid until surrendered, suspended or revoked.

## QUALITY ASSURANCE INTERNATIONAL

9191 Towne Centre Drive, Suite 510 • San Diego California, U.S.A. • (858) 792-3531 • Fax: (858) 792-8665



# Organic System Plan Summary

Company: Ribus, Inc.  
 20 S. Central Ave.  
 St. Louis, MO 63105  
 USA

Operation Type: Handler (Trader)

Certification Number: 104291-B

First Certified Date: 05/19/2004

Next Annual Monitoring Date: 03/02/2005

## Organic

Category	Product	ID Mark	Compliance	Date Added
Rice Products	Nu Bake Rice Bran Extract	Ribus	NOP	05/19/2004
Rice Products	Nu Rice Bran Extract	Ribus	NOP	05/19/2004
Rice Products	Nu Rice Eutical Rice Bran Extract	Ribus	NOP	05/19/2004
Rice Products	Oryza Mul Rice Bran Extract	Ribus	NOP	05/19/2004

The above information is provided as a description of the organic system under certification. This document does not replace the organic certificate. It is provided as customer service to assist in the representation of the certified organic products.

Authorization \_\_\_\_\_

10/21/2004



## Product Specifications

### Product Analysis:

### Nu-FLOW 70 R & 235 R

Protein	3% - 7%
Fat	0% - 3%
Carbohydrate	22% - 34%
Ash	14% - 20%
Crude Fiber	20% - 44%
Moisture	≤10%

**Description:** Patented organic silica, light tan in color, used to replace Silicone Dioxide (a synthetic) as an anti-caking agent or a flavor carrier.

### Typical Use Rates:

Anti-Caking Agent	1:1 to 1.2:1 replacer for SiO <sub>2</sub>
Flavor Carrier	Determined by processor's needs
Pelletizing / Tableting	" " " "
Spray Drying	" " " "

### **Benefits:**

- Eliminate a Synthetic
- Clean-up Labels
- Achieve a 95% Organic Status

### **Particle Size Options:**

- Nu-FLOW 70 R: < 70 micron
- Nu-FLOW 235 R: 235-750 micron
- Contact RIBUS about custom sizes

**Label:** "Rice Concentrate" (for clean label declaration)

**Packaging:** Nu-FLOW 235 R: 35 lbs bag in a box / 27 boxes per pallet = 945 lbs  
Nu-FLOW 70 R: 45 lbs bag in a box / 27 boxes per pallet = 1,215 lbs

**Storage:** Store at <90° F (32 Celcius) and >32° F (0 Celcius)

**Shelf Life:** 2 years

### **Certifications:**

- Certified Organic – QAI
- Kosher Parve OU

©2006 RIBUS, Inc., Nu-FLOW™ is a trademark of RIBUS, Inc. This product is patent pending. Made in the USA



## REPLACER FOR SILICONE DIOXIDE (SiO<sub>2</sub>)

Organic Nu-FLOW™ effectively replaces Silicone Dioxide (and other synthetics) in certified organic systems requiring anti-caking and flow aids. Additional applications include use as a flavor carrier when plating flavors. Made from certified organic vegetation that contains silica, Nu-FLOW provides Functionality + Clean Labels.

### Features

Certified Organic

Anti-Caking Agent

Flavor Carrier / Plating

Pelletizing / Tableting

Vegetative Origin

Non-Allergenic

### Benefits

Clean Label, replace Synthetics with Organic (QAI Certified)

Improve Product Flow, Decrease Lumps, Reduce Stickiness (naturally)

Dilute Flavor / Spice Concentrates, While Eliminating Lumps

Inert Particles with Surface Adhesion to Receive Plated Flavors

Excipient to hold shape

Made from Certified Organic Plants, Clean Label, Non-Synthetic

Rice based, Non-GMO ingredient that does not require allergen labeling.

### Use Rates Per Application:

Anti-Caking

Flavor Carrier

Pelletizing / Tableting

Spray Drying

1:1 to 1.2:1 replacer for SiO<sub>2</sub>

Determined by Processor's Needs

" " " "

" " " "

**Suggested Label Declaration (if required): "rice concentrate"**

**Recommended Mixing:** Dry blend Nu-FLOW with dry ingredients or co-spray dry.

Organic Nu-FLOW is functional plant silica (from organic vegetation) that delivers functionality and a clean label.

***Functionality + Clean Labels (organically)!***

File:corp/office/literature/nuflow/NFapplicationsheet print