Silicon Dioxide

Handling/Processing

Identification of Petitioned Substance

Chemical Name:
Silicon Dioxide

CAS Number:
7631-86-9[1]

Other Names:
Silica
Silicic anhydride

Other Codes:
INC 551
RTECS: VV7310000

Characterization of Petitioned Substance

Composition of the Substance:

The chemical compound silicon dioxide is also known as silica (from the Latin *silex*). Silica is found in the earth's crust; it is commonly in the crystalline state and rarely in an amorphous state. Silicon dioxide is composed of one atom of silicon (Si) and two atoms of oxygen (O) resulting in the chemical formula SiO_2. It is comprised of 46.75% Si and 53.26% O (Merck Index, 2006).

The basic structural unit for silicon dioxide is a tetrahedral arrangement of four oxygen atoms surrounding a central silicon atom with an average of two oxygen atoms shared by each silicon in an infinite three-dimensional polytetrahydral network, see Figure 1.

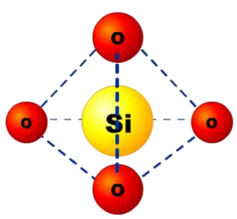

Fig. 1

Properties of the Substance:

Silicon dioxide has a molecular weight of 60.08 g/mol. It has the lowest coefficient of expansion by heat of any known substance. Silica is not soluble in either water or organic solvents, but it is soluble in hydrofluoric acid. Heating with concentrated phosphoric acid may slowly dissolve silicon dioxide as well (Merck Index, 2006). Silicon dioxide exists in the crystalline and amorphous forms. Their physical states are easily differentiated by X-ray diffraction; the crystalline form exhibits a well-defined diffraction pattern while the amorphous form does not. The density of crystalline silica (e.g. quartz) and amorphous silica are 2.65 and 2.2 g/cm^3, respectively. Silica is transparent, tasteless, crystal or amorphous powder. The amorphous form of silica may be dissolved by hot concentrated alkaline solutions, but the crystalline form of silica generally is not soluble (Merck Index, 2006).

Amorphous silica with submicron particle size has a variety of highly unique physical and chemical properties and potential as an additive in a variety of processing industries (Villota and Hawkes, 1986).

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[1] This is the general CAS Number for either crystalline or amorphous silica. For a chart of SiO_2 CAS No., see the following link: http://www.ima-eu.org/fileadmin/eurosil/silicacas.pdf .

The physical characteristics of silica are dependent on their mode of manufacture. Its surface may be made up of free silanol groups (Figure 2), hydrogen-bonded silanol group, and siloxane groups (Figure 3).

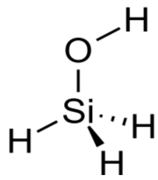

Fig. 2 Silanol group

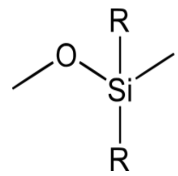

Fig. 3 Siloxane group

Furthermore, an individual silicon atom on the silica surface may be substituted with aluminum coordinated with four oxygen atoms as in the aluminated ion, $Al(OH)_4^-$. This is important in considering compatibility of amorphous silica and its host powder when using it as an anticaking agent as well as a dispersing agent (stabilizer) in low pH systems. Amorphous silica is also capable of rehydroxylating in aqueous systems to form a high ratio of silanol to siloxane groups. In addition, depending on the hydrophobicity of the solvent media, it may form a network-like structure through hydrogen bonding. These capabilities give amorphous silica its gelling and thickening abilities in various solvent system (Villota and Hawkes, 1986).

The most outstanding characteristics of amorphous silica, particularly synthetic amorphous silica, are their small particle size and high specific surface area, which determine their numerous applications (EPA/600/R-95/115, 1996).

Specific Uses of the Substance:

According to FDA, a synthetic amorphous silicon dioxide is used as a food additive and it serves more than one function:

- An anti-caking agent in foods and animal feeds.
- A stabilizer in the beer production and removed from the beer by filtration prior to final processing.
- An adsorbent for dl-α-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use.
- A carrier, such as a component of microcapsules for flavoring oils.
- A defoaming agent.

Moreover, silica may be use as corrosion-resistant coatings in various types of cans and moisture-impermeable films as well as for rheology control in paints, silicon rubbers, polyester compounds, antiblocking agents, dental formulations, emulsions, cosmetics, excipients in pharmaceuticals, etc.

Silicon dioxide is also commonly used as an inert carrier in dry pesticides, a soil conditioner, and a turf soil supplement. Its most commonly insecticidal use is for control of stored grain insects (EPA RED, List D, Case 4081, 1991).

Approved Legal Uses of the Substance:

EPA— "7631-86-9 Silicon dioxide (crystalline-free forms only)" is listed under the List 4A – Minimal Risk Inert Ingredient. In addition, silicon dioxide is registered (OPP Chemical Code No: 72605) as an active ingredient in insecticide and/or acaricide for use to control a variety of insects/mites in and around domestic/commercial dwellings, ornamental gardens, in kennels, and on domestic pets.

FDA— In 21 CFR §172.480 *Silicon dioxide* and §573.940 *Silicon dioxide* are stated "(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." Uses of silicon dioxide are listed in Table 1.

Table 1. FDA Regulations, 21 CFR

Regulatory Citations		Technical Effects	Status	Use Limits
SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION	Part 172—Food Additives Permitted for Direct Addition to Food for Human consumption. Subpart E—Anticaking Agents.			
	§172.480 Silicon dioxide	Anticaking agent	Used in only those foods in which the additive has been demonstrated to have an anticaking effect.	Not to exceed 2% by weight of the food.
		Stabilizer	Used in the production of beer and is removed from the beer by filtration prior to final processing.	
		Adsorbent	For dl-a-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use.	Not greater than that required to accomplish the intended physical or technical effect.
	§172.230 Microcapsules for flavoring substance	Adjuvant	Silicon dioxide can be a component of microcapsules.	Complying with §172.480.
	Part 173—Secondary Direct Food Additives Permitted in Food for Human Consumption. Subpart D—Specific Usage Additives. §173.340 Defoaming agents.	Defoaming	Used in processing foods.	As defined in §172.480
	Part 160—Eggs and Egg Products. Subpart B—Requirements for Specific Standardized Eggs and Egg Products. §160.105 and §160.185	Anticaking	Silicon dioxide may be added as an optional anticaking ingredient in the products of dried eggs and dried egg yolks	Either complying with §172.480 or use ≤ 1% of SiO_2 and < 2% of sodium silicoaluminate by weight of the finished food.
	Part 182—Substances Generally Recognized As		Silicon dioxide used in food packaging that is	

	Safe. Subpart A—General Provisions. §182.90 Substances migrating to food from paper and paperboard products		GRAS for its intended use.	
SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS	Part 573—Food additives permitted in feed and drinking water of animals. Subpart B—Food additive listing. §573.940 Silicon dioxide	Anticaking agent and/or grinding aid	May be used in animal feed	Not to exceed 2% by weight of the finished feed.

USDA— Silicon dioxide is listed on NOP the National List of Allowed and Prohibited Substance, 7 CFR §205.605 (b) Synthetics allowed.

Action of the Substance:

Silicon dioxide is commonly used as an anticaking agent, which prevents lumping by keeping foods from absorbing moisture, in granular products. It not only improves flow properties but also increases speed of dispersion by keeping the food particles separated and permitting the water to wet them individually instead of forming lumps. It can also be used as a defoaming agent to reduce foaming cause by proteins, gases, nitrogenous materials, or others, which may interfere with processing or the desired characteristics of the end-products if without using it.

For the insecticidal applications, silica employs a physical mode of action to control insects. Since it is abrasive and acts as a desiccant, it removes the oily, protective film that covers insects' bodies, causing them to dry out and die (EPA RED, List D, Case 4081, 1991).

Status

Domestic:

EPA — Inert pesticide ingredients in the List 4A is updated in August, 2004. Moreover, silicon dioxide is first registered as a pesticide product in 1960 and reregistered in 1991. Because of its low toxicity when ingested, it has been exempted from tolerance, or legal residue limit, requirement (EPA RED, list D, Case 4081, 1991).

FDA — See the above, the Approved Legal Uses of the Substance section.

International:

Codex — Silicon dioxide amorphous (E 551) is a food additive that is included in the Codex General Standard for Food Additives (GSFA) General Conditions of Table 3. Functional Classes: anticaking agent and filter aid. It may be used at the maximum levels of 10,000 and 15,000 mg/kg in the dried whey and whey products (excluding whey cheeses) and in the powdered sugar and powdered dextrose products, respectively. For other foods, see GSFA Table 3 Provisions[2], silica may be used under the condition of good manufacturing practices.

European Union — 'E 551 silicon dioxide' is listed in Directive 92/2/EC of the European Parliament and of the Council, February 20, 1995.

[2] http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=284

Canada — Silicon dioxide is in the list of food additives permitted for use in Canada. It may be used as an anticaking agent and miscellaneous agent (such as filtering and clarifying agent in beer, foaming agent in beverages, tableting aids).

Japan — "Silicon Dioxide (Silica Gel) (229)" is listed on Table 1 related to Articles 12 and 21 of the Food Sanitation Law Enforcement Regulations. Last amendment November 29, 2005. Ministry of Health, Labor, and Welfare Ordinance No. 166.

IFOAM — "Silicon dioxide (Amorphous)" is listed under the section III (*Additives and Processing Aids*) of *IFOAM Indicative List of Substances for Organic Production and Processing*. It is used as a processing aid for wine, fruit and vegetable processing, and gelatin production.

Codex (organic) — Silicon dioxide (Amorphous) as an additive is permitted to use in herbs, spices, seasonings, and condiments (e.g. seasonings for instant noodles); also, as a processing aid, it may be used for gel or colloidal solution. Above information are listed in ANNEX 2 of the *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods*.

European Union (organic) — Silicon dioxide is listed under Section A (*Food Additives, including Carriers*) in ANNEX VIII of the Commission Regulation (EC) No 889/2008 of September 5, 2008. It is used in preparation of foodstuffs of plant origin as an anticaking agent for herbs and spices.

Canada (organic) — Silicon dioxide is listed under Subsections *6.3 (Non-organic Ingredients Classified as Food Additives)* and 6.6 (*Processing Aids*) of Section *6 (Permitted Substances Lists for Processing)* of the *Organic Production System Permitted Substances Lists*. Amended October 2008 and December 2009 by Canadian General Standards Board.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21).

Silicon dioxide is abundantly found in the earth's crust. Silica occurs naturally in a variety of crystalline and amorphous forms. It appears as sand or quartz in soils and sediments; and as biogenic silica in organisms (such as diatoms, radiolarians, or silicoflagellates) and in plants (such as grass, rushes, rice or sugar cane) (OECD SIDS, SIAM 19, 2004). Synthetic silica is prepared for various purposes and used in particular applications; for example, synthetic amorphous silica can be used as a flow agent in powdered foods, or to absorb water in hygroscopic applications.

Crystalline silica

According to the Hazardous Substances Data Bank (HSDB) of Toxicology Data Network (TOXNET), there are two ways to produce crystalline silica: (I) the processing of naturally occurring quartz and (II) the hydrothermal culturing of quartz (a synthetic quartz crystal). Hydrothermal synthesis consists of crystal growth or reaction at high pressure and temperature in aqueous solution in sealed steel autoclaves.

Amorphous silica

(I) Naturally occurring sediment or rock that contain the amorphous form of silica include diatomite or diatomaceous earth, a hydrated form (e.g. opal), and an unhydrated form (e.g. flint). Diatomite is mined exclusively by opencast methods, using bulldozers and other similar equipment to remove the material (HSDB, TOXNET).

(II) Synthetic amorphous silica can be manufactured by three methods: a vapor-phase hydrolysis process, a wet process, or a surface-modified treatment (IARC, Vol. 68, 1997).

(1) The vapor-phase hydrolysis process produced pyrogenic or fumed silica (CAS No. 112945-52-5) is based mainly on the combustion of volatile silane, especially silicon tetrachloride, in an oxygen-hydrogen burner. Primary particles (7-50 nm particle size) of amorphous silica fuse together in the high-temperature flame to yield stable aggregates of between 100 and 500 nm in diameter. These aggregates form micron-sized agglomerates. The finely divided silica is separated from the hydrochloric acid-containing off-gas stream in filter stations. The hydrochloric acid content of the product is commonly reduced to less than 100 ppm by desorbing the hydrochloric acid with air in a fluid-bed reactor.

(2) The wet process is based mainly on the precipitation of amorphous silicon dioxide particles from aqueous alkali metal silicate solution by acid neutralization. Usually, sulfuric acid is used. Depending on the final pH of the solution, the following two different classes of synthetic amorphous silica can be obtained: (i) precipitated silica (CAS No. 112926-00-8) obtained in neutral or alkaline conditions; (ii) silica gel (CAS No. 112926-00-8) obtained under acidic condition. The main manufacturing steps include precipitation, filtration, washing, drying, and grinding.

(3) Surfaces of modified silica have been rendered hydrophobic, for example, by silylation with dimethyl dichlorosilane. All forms of synthetic amorphous silica can be surface-modified either physically or chemically. Most common treating chemical agents for silylation are organosilicon compounds. According to IARC's silica report (Vol. 68, 1997), less than 10% of the total production volume of synthetic amorphous silica is surface-modified.

<u>Evaluation Question #2:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources. (7 U.S.C. § 6502 (21))

The most prevalent processes used to manufacture silicon dioxide are stated in the Food Chemical Codex (FCC) (2010-2011). The monograph of FCC stipulated that synthetic amorphous silica is produced either by a vapor-phase hydrolysis process or by a wet process. Both methods are described in Evaluation Question #1.

The IARC silica report (Vol. 68, 1997) stated that large quantities of synthetic amorphous silica are produced as pyrogenic silica and wet process silica (precipitated silica and silica gels). The vapor-phase hydrolysis process yields pyrogenic silica which is produced by the hydrolysis of chlorosilane, such as silicon tetrachloride vapor in a flame of hydrogen and oxygen at high temperatures (1800° C). Silicon tetrachloride can be made by the treatment of silicon with chlorine. Pyrogenic or fumed silica occurs as a white, fluffy, non-gritty powder of extremely fine particle size and is hygroscopic (FCC, 2010-2011). The wet process yields precipitated silica[3], silica gel[4], or colloidal silica[5]; these products are obtained as hydrates or contain surface-adsorbed water. This process generally involves a solid-phase separation from a sodium silicate solution. Sodium silicate is made by fusing of silica sand with soda ash in an open hearth furnace. The wet process silica occurs as white, fluffy powders or as white, microcellular beads or granules and is hygroscopic or absorbs moisture from the air in varying amounts (FCC, 2010-2011).

[**Note**: According to the FDA's regulations, silicon dioxide (as a food additive) should be **manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect** (21 CFR §172.480 and §573.940). Moreover, silicon dioxide listed under EPA List 4A is crystalline-free forms only.]

[3] Precipitated out from an aqueous solution.

[4] A coherent, rigid, continuous three dimensional network of spherical particles of colloidal microporous silica.

[5] A stable dispersion of discrete, colloid-sized particles of amorphous silica in an aqueous solution.

Evaluation Question #3: Provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Of the several crystalline polymorphs of silica found in nature, quartz is by far the most common being abundant in most rock types, notably granites, sandstones, quartzites, sands and soils; cristobalite and tridymite are found in volcanic rocks.

Amorphous silica is found in nature as biogenic silica and as silica glass of volcanic origin. Biogenic silica is any silica originating in living matter (known sources include bacteria, fungi, diatoms, sponges, and plants); the two most relevant biogenic silicas are those associated with fossilized diatoms and crop plants.

Diatomaceous earth (CAS No. 61790-53-2), originates from the skeletons of diatoms deposited on sea floors, contains typically 90% biogenic silica with small amounts of cristobalite and quartz (IARC, Vol. 69, 1997).

[Note: In the FDA regulations, diatomaceous earth is used or intended for use as inert carrier or anticaking agent in animal feeds in an amount not to exceed 2% by weight of the total ration, see 21 CFR §573.340; diatomaceous earth filler migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for its intended use, see 21 CFR §182.90. According to EPA, diatomaceous earth is used or intended for use for control of insects in the areas of food/feed processing and food/feed storage: that the food or feed is removed or covered prior to such use (40 CFR §180.1017); diatomaceous earth (less than 1% crystalline silica) is listed under List 4A—Minimal Risk Inert Ingredients. Furthermore, it is listed on NOP the National List of Allowed and Prohibited Substance (7 CFR §205.605 (a) Nonsynthetics allowed. "Diatomaceous earth—food filtering aid only").]

A variety of plants also produce biogenic silica. Internal silicification of plant tissues promotes structural integrity and affords protection against plant pathogens and insects. The silica content is especially high in grasses, and silica can account for approximately 20% of the dry weight of rushes, rice and sugar cane. Amorphous silica in plants may be deposited as nodules or phytoliths. Some of the amorphous silica in plants (e.g. sugar cane, canary grass, wheat, rice, conifer needles) exists as fibers or spicules of various forms (IARC, Vol. 69, 1997).

In the invention of US Patent (No. 6843974 B2), it provides a method which is capable of extracting high purity amorphous silica from seed shell of various herbaceous plants (Kang, 2005). However, no information reviewed specifically address using seed shell of herbaceous plants for commercially produced amorphous silica.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices. (7 CFR § 205.600 (b)(5))

In accordance with 21 CFR §182.90, silicon dioxide is considered as a GRAS substance, which migrates to food from paper and paperboard products used in food packaging. It is also included in the Database of Select Committee on GRAS Substances (SCOGS) Reviews. This GRAS substance was evaluated by SCOGS in 1979. The SCOGS concluded that there was no evidence in the available information on silicon dioxide that demonstrated, or suggested reasonable grounds to suspect, a hazard to the public when they were used at levels at that time or might reasonably be expected in the future.

In GRAS Notice Inventory, the status of GRN No. 298 (silicon dioxide) is stated as "At notifier's request, FDA ceased to evaluate the notice". According to FDA's Agency Response Letter GRAS Notice No. GRN 000298, FDA received the notice submitted by Cabot Corporation and designated it as GRAS Notice No. GRN 000298 on July 14, 2009. The notice informed FDA of the view of Cabot Corporation that silicon dioxide was GRAS, through scientific procedures for use in a variety of foods and food-packing materials.

On October 9, 2009, Cabot Corporation sent a letter to FDA to withdraw its notice; FDA ceased to evaluate its notice, with immediate effect.

Evaluation Question #5: Describe whether the primary function/purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative. (7 CFR § 205.600 (b)(4))

No information sources reviewed specifically address the primary function/purpose of silicon dioxide as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics. (7 CFR § 205.600 (b)(4))

Silica is used mainly as an anticaking agent to reduce the tendency of individual particles of a foodstuff to adhere to one another. Some products, which contain one or more hygroscopic substances, require the addition of an anticaking agent to inhibit formation of aggregates and lumps and thus retain the free-flowing characteristic of the products. Many food products, when stirred into water, tend to form lumps which are difficult to disperse or dissolve. Therefore, silica also acts as a dispersant for powdered products. Furthermore, silica can be a stabilizer to prevent chill haze during the storage period in the beer production and is removed from the beer by filtration prior to final processing.

No information was indentified to suggest that silicon dioxide can be used primarily to recreate or improve flavors, colors, or nutritive values lost in processing.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used. (7 CFR § 205.600 (b)(3))

No information sources reviewed specifically address the use of silicon dioxide affects the levels of nutrients commonly found in the food products.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance. (7 CFR § 205.600 (b)(5))

According to the specification of silicon dioxide in Food Chemical Codex (2010-2011) and the Joint FAO/WHO Expert Committee on Food Additives (Monograph 1, 2006), they stipulated the impurity acceptable criteria is not more than 5 mg/kg of lead.

No information was indentified to suggest that the petitioned substance contains residues of heavy metals or other contaminants in excess of FDA's Action Levels for Poisonous or Deleterious Substances in Human Food.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i))

Silica dust is produced during its manufacture (such as rock cutting, drilling, crushing, processing of diatomaceous earth) and use. Environmental emissions of silica can arise from natural, industrial, and farming activities. However, no data on ambient air concentrations of amorphous silica are located, and ambient levels are not well quantified for crystalline silica, principally because existing measurement methods, although capable of distinguishing crystalline silica (e.g. X-ray diffraction), are not designed to deal with the large amounts of nonsilica particles in ambient air (EPA/600/R-95/115, 1996). Exposure levels are considered the highest in occupations involved with packing, weighing, reprocessing, and cleaning (HSDB, TOXNET).

In EPA Reregistration Eligibility Document (RED), List D, Case 4081 (1991), it stated that silicon dioxide's primary component is found in common minerals like quartz, sand, and agate; and silica gel is simply an amorphous form of silicon dioxide. These materials are ubiquitous, and unlikely to react chemically with any other substances in the environment. For ecological effects, there is no evidence to suggest that the use of these materials as pesticides, in accordance with approved labeling, presents a hazard to nontarget organisms or the environment.

EPA concluded that silicon dioxide and silica gel do not pose unreasonable risks to the environment, including non-target organisms, when used at their registered levels. This conclusion is based on the belief that silicon dioxide and silica gel are chemically unreactive in the environment, occur naturally in various forms and are practically non-toxic to non-target organisms (EPA RED, List D, Case 4081, 1991).

The Organization for Economic Co-operation and Development (OECD) Screening Information Data Sets (SIDS) published SIDS Initial Assessment Report on synthetic amorphous silica and silicates. The synthetic amorphous silica including silicon dioxide (CAS No. 7631-86-9), silica gel (CAS No. 112926-00-8), precipitated silica (CAS No. 112926-00-8), and pyrogenic silica (CAS No. 112946-52-5) were subject of this evaluation. This report stated that synthetic amorphous silica are solids in powder form which have a low water solubility, based on the sum of soluble SiO_2 and cations (water-soluble fraction): ≤ 70 mg/l at 20 °C. They are not volatile and have no lipophilic character. These compounds will be distributed mainly into soils/sediments and weakly into water and are expected to combine distinguishably with the soil layer or sediment due to their chemical similarity with inorganic soil matter. The bioavailable forms of silica are dissolved silica [$Si(OH)_4$] almost all of which is of natural origin. The ocean contains a huge sink of silica and silicates where a variety of the marine habitat (diatoms, radiolarians, and sponges) is able to exploit this resource as a construction material to build up their skeletons. Based on the chemical nature of silica and silicates (inorganic structure and chemical stability of the compound: Si-O bond is highly stable), no photo- or chemical degradation is expected. Biodegradation is not applicable to these inorganic substances.

For aquatic effects, the report indicated that studies on fish, daphnia, and algae using excess loadings of synthetic amorphous silica showed no acute toxicity, although physical effects on daphnia were observed in tests using unfiltered test medium. There are no chronic aquatic toxicity data, but due to the known inherent physico-chemical properties, absence of acute toxic effects as well as the ubiquitous presence of silica/silicates in the environment, there is no evidence of harmful long-term effects arising from exposure to synthetic amorphous silica/silicates (OECD SIDS, SIAM 19, 2004).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance. (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4))

According to SCOGS Reviews on the silicon dioxides report, the Select Committee stated that silicon dioxide and various silicates are present in practically all natural waters, animals, and plants; and are part of the normal human diet. Silicon compounds consumed as added food ingredients contribute only a minor proportion of the total dietary silicon intake. The estimated possible human intake of sodium aluminosilicate, the predominant silicate added to foods in the US, is approximately 0.3 mg/kg body weight/day. Silicon compounds that are GRAS/food additive for use as direct food ingredient, except potassium and sodium silicates, are insoluble or very slightly soluble in water and appear to be biologically inert. The water-soluble silicates are also of low acute toxicity. No significant tissue accumulation, pathology, or toxicity has been reported from the ingestion of those insoluble or very slightly soluble GRAS/food additive silicon compounds for which data are available (SCOGS Reviews, Report No. 61, 1979).

In the EPA RED for silicon dioxide and silica gel (List D, Case 4081, 1991), the Agency indicated that available studies demonstrated silicon dioxide and silica gel have moderate to low acute toxicity. These pesticides have been placed in Toxicity Category III for acute oral and dermal effects (Note: Toxicity Category I indicating the highest degree of toxicity, and IV the lowest). Similarly, an inhalation study and eye and dermal irritation studies suggest moderate to low toxicity. With regard to subchronic and chronic effects, crystalline silicon dioxide has long been associated with silicosis, a progressive lung disease which may result in lung cancer in humans. However, amorphous silicon dioxide (used in pesticide formulations) has not been associated with silicosis. The International Agency for Research on Cancer (IARC) conducted an in-depth evaluation of the potential carcinogenicity of silicon dioxide. In making the overall evaluation, the Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Carcinogenicity may be dependent on inherent characteristics of the crystalline silica or on external factors affecting its biological activity or distribution of its polymorphs. The final conclusion based upon all the available data was that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to human (Group 1) and that amorphous silica is not classifiable as to its carcinogenicity to humans (Group 3) (IARC, Vol. 68, 1997).

People may be exposed to silicon dioxide and silica gel through their diet, since these pesticides may be applied to certain crops and used in and around food handling and preparation areas. However, due to their negligible toxicity, silicon dioxide and silica gel have been exempted from tolerance, or legal residue limit, requirements (EPA RED, List D, Case 4081, 1991). Workers may inhale particles of silicon dioxide and silica gel when applying these dust, aerosol, or crack-and-crevice injection formulations. Current product labels for dust formulations require the use of a dust mask for prolonged periods of use. EPA believes that applicators' dermal exposure to these products also may be significant. However, since applications and exposures normally occur only several times a year (or less), the Agency is not requiring additional protective clothing or other changes in use, at this time (EPA RED, List D, Case 4081, 1991).

Therefore, EPA concludes that the human health risk from exposure to silicon dioxide and silica gel is low and not unreasonable. These pesticides are of moderate to low acute toxicity. Dietary exposure is believed to be insignificant from a toxicological standpoint. Applicator exposure may be significant for each application; however, these products generally are used infrequently (EPA RED, List D, Case 4081, 1991).

Evaluation Question #11: Provide a list of organic agricultural products that could be substituted for the petitioned substance. (7 CFR § 205.600 (b)(1))

According to the petitioner, RIBUS, Inc. of St Louis, MO developed, in 2007, an organically certified method to produce a rice-based alternative (Nu-FLOW, which is a trademark of RIBUS, Inc.) from ground organic rice hulls for the petitioned substance. Rice hulls contain a high concentration of amorphous silica. This rice-based alternative provides the same functionality as silicon dioxide in the above reference applications. It is also certified organic by Oregon Tilth and is accepted as organic by Certisys in the EU. However, the petitioner did not provide any information regarding manufacture of or method to produce this product.

According to a patent (World Intellectual Property Organization, International Publication No. WO 2008/016701 A2) on *Biogenic Silica From Silica-containing Plant Material Such As Rice Hulls* by Hammond and Peirce (2008), this invention is to obtain a biogenic silica from a plant material (such as rice hulls, rice straw, or other plants) for use as an anticaking agent, excipient, or flavor carrier. The usage level may be the same as synthetic amorphous silicas. However, larger quantities may be required to compensate for the lower concentration of silica as compared to fumed silicas (Hammond and Peirce 2008).

As described in this patent, a plant material such as rice hulls is ground and then screened into a finely divided state. The rice hulls can be milled to particle sizes ranging from about 10 microns or less to about 1500 microns, which is application dependent. The amount of silica may be concentrated by carbon reduction through enzymatic treatment or burning.

For enzymatic treatment, an enzyme(s) can be added to rice hulls to digest carbon-containing and/or protein-containing compounds under proper conditions of pH, temperature, and moisture. During digestion, those compounds are broken down into soluble products in the water phase. After digestion, the solids that contain biogenic silica are separated from the liquid phase by filtration or centrifugation. The solids are then dried, ground, and screened (Hammond and Peirce, 2008).

The carbon content of rice hulls can also be reduced by combustion in a burner. The ash remaining after burning may be washed and then dried. Rice hulls prior to burning or the ash may be leached with an acid (such as hydrochloric, sulfuric, nitric acids) to remove minerals other than silica (Hammond and Peirce, 2008).

In some instances an antimicrobial treatment may be added to the products to reduce the microbial count to an acceptable level. The treatment may include pasteurization or irradiation (Hammond and Peirce, 2008).

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