



Designing the GreenShield™ Finish – Selecting “GRAS” Components with an Established Safety-Profile.

The term “GRAS” is an acronym used by the FDA and EPA for “generally recognized as safe”. Note that amorphous silica has several names and variants and is also commonly referred to as precipitated silica, colloidal silica, fumed silica, silicon dioxide and hydrated silica. It is important to note that it is distinct from crystalline silica.

GreenShield™ was developed to lower the impact of stain resistant finishes on the environment by reducing the amount of fluorochemicals necessary in the finish, and further by selecting components (to replace the fluorochemicals) that have a clear and established safety profile. Our nanomaterial-based approach utilizes amorphous silica – a material that has been used in industry for more than 100 years and is approved by the FDA and EPA in products for direct human consumption. Amorphous silica (SiO₂) is derived from sand and is one of the most abundant materials on earth. It is commercial available as “colloidal” dispersions in water at nanoscale-size; its’ particle size can be controlled, and may vary from a few nanometers to a few microns. Products containing amorphous silica are used by a multitude of industries, by the general public (consumers), in health-care and pharmaceuticals, in cosmetics and even in food-products for both animal and human consumption. Because of its’ long history, and clearly established safety and environmental profiles, we believe the use of nanoscale amorphous silica in the GreenShield™ product line to replace fluorochemicals, represents a clear safety and environmental benefit for the industries and user’s of products that contain the GreenShield™ finish.

Amorphous Silica and its’ Uses (general)

Nanosize, amorphous silica has been used in industry for more than 100 years and finds its way into many consumer products both in the wet “colloidal state” and in the dry state. The information and quotations below are pulled from the internet and a variety of sources including the FDA and EPA, and highlight the many applications of amorphous silica, its safety- and environmental-profiles. For convenience, the most relevant sections of the FDA publications are highlighted in yellow.

Information Regarding Amorphous Silica and its' FDA and EPA "GRAS" Status.

From <http://www.integratedhealth.com/excipients.asp>

"Statement on Additives, Fillers, And Other Excipients"

2) Silica / Silicon Dioxide (GRAS listed) - Silicon Dioxide is widely used in pharmaceutical formulations, cosmetics, and food products. It is also widely used in orally-dosed nutritional products and regarded as an essentially nontoxic, nonirritant excipient. Silicon Dioxide readily absorbs large quantities of water from its surroundings, and does this without itself liquefying. The major application of silica in solid-dosage forms is as a glidant and anti-static agent to improve the flow properties of granulations in high-speed tablet and capsule machines. Particulate flow has a direct effect on weight uniformity and plays an important role in solid-solid blending and powder homogeneity.

Glidants reduce friction between particles and function to improve the flow of granulations in the manufacturing process. Silica also fills surface irregularities in granules, reducing inter-particulate friction and improving flow. Glidants also prevent the segregation and separation of granules caused by excessive vibration in a tablet press or capsule press. The presence of Silica in a tablet granulation prevents cavitation or surging of the powder blend that often occurs in direct compression formulations. Uniformity in tablet hardness and tablet weight results from formulations flowing evenly into the die cavity during tableting operations. Silica is generally used as a glidant at a concentration range of 0.1% - 0.75%, and is typically used at the 0.5% level.

From http://www.tomsomaine.com/toms/ifs/hydrated_silica.asp *Ingredient Fact Sheet:*

Hydrated Silica

What is it?

Hydrated silica is a derivative of silica (silicon dioxide) , an abundant compound that forms about 12% of the earth's surface. Sand and obsidian are common forms of silica. In hydrated form, this ingredient is an odorless, tasteless white gelatinous substance which is chemically inert. This same ingredient may also go by the names amorphous silicon dioxide, silicic acid, or silica gel.

What does it do?

Hydrated silica is a mild abrasive which gives toothpaste a smoother "gel" quality. Combined with calcium carbonate, it helps to safely remove plaque with brushing. We mix it into our childrens' flavors and our Wintermint flavor in combination with a regular toothpaste base to give these flavors a unique half-paste, half-gel consistency. The ingredients are thoroughly blended, however: the gel and paste ingredients are not made into distinct "stripes" within the tube. In our Antiplaque Tartar Control & Whitening flavors, the hydrated silica we use is milled to produce a slightly larger particle size (an average particle size of 10 microns, versus 8 microns, on average, in our children's and Wintermint flavors). This makes it a better cleaner, so that it can help to remove stains that have formed on teeth.

What are the alternatives?

Hydrated silica represents the very safest and most natural choice for providing mild abrasivity and gel-like consistency. It is an ideal ingredient because it adds no discernible taste or odor to the end product.

What are the risks?

Hydrated silica has a long history of safe use as an ingredient in food products. It is listed by the US Food & Drug Administration to be Generally Recognized As Safe (GRAS) and has no known toxicity or carcinogenicity.

In the 1980's concerns were raised about the use of "silica," a term commonly used to describe both hydrated silica and crystalline silica. Crystalline silica is a toxin and evidence suggests it is a carcinogen as well. In response to the confusion created by the two ingredients sharing a common name, the Chemical Abstracts Services (CAS) created a new catalog number for hydrated silica to more effectively differentiate it from its toxic cousin, crystalline silica.

The only potential risk involved in using hydrated silica is that it could be sourced in such a way that it is contaminated by crystalline silica. We require our supplier for this ingredient to use a test method called X-ray diffraction to conclusively prove that the hydrated silica we purchase is not contaminated by crystalline silica.