

WACKER

CREATING TOMORROW'S SOLUTIONS

PUR ITY

WITH HDK®.



COLLOIDAL SILICON DIOXIDE | PHARMA, NUTRITION

HDK® – FOR PHARMACEUTICAL,
FOOD AND FEED APPLICATIONS

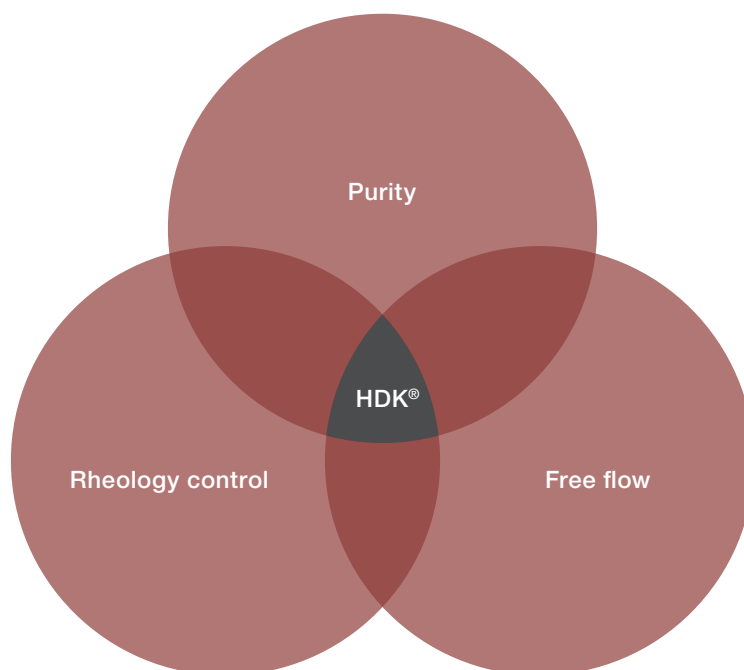


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FOR THE PROPERTIES YOUR PRODUCT NEEDS

HDK® – Versatile and Effective

WACKER has been producing and refining HDK® silica for 50 years. Our integrated closed-loop technology, statistical process control and highly efficient reactor dynamics produce high-purity inorganic, colloidal silicon dioxide. This silica is ideal for pharmaceutical and food applications.



Indispensable in Pharmaceuticals

HDK® pyrogenic colloidal silicon dioxide is an excipient for pharmaceuticals. It is a highly effective tableting aid, provides free flow for powders and ensures the right rheology in liquid formulations. HDK® greatly enhances the efficiency of processes like granulation and tableting. For liquid pharmaceuticals, HDK® ensures reliable performance throughout storage and application.

Focused on Quality

With our extensive experience in the production of pyrogenic colloidal silicon dioxide, we are able to provide ultra-high-purity products which are consistent from batch to batch, allowing our customers to enjoy uniform product performance. With competence centers in the major regions of the world, we are here to meet your needs.

HYDROPHILIC HDK®

Pyrogenic Silica with a High Specific Surface Area

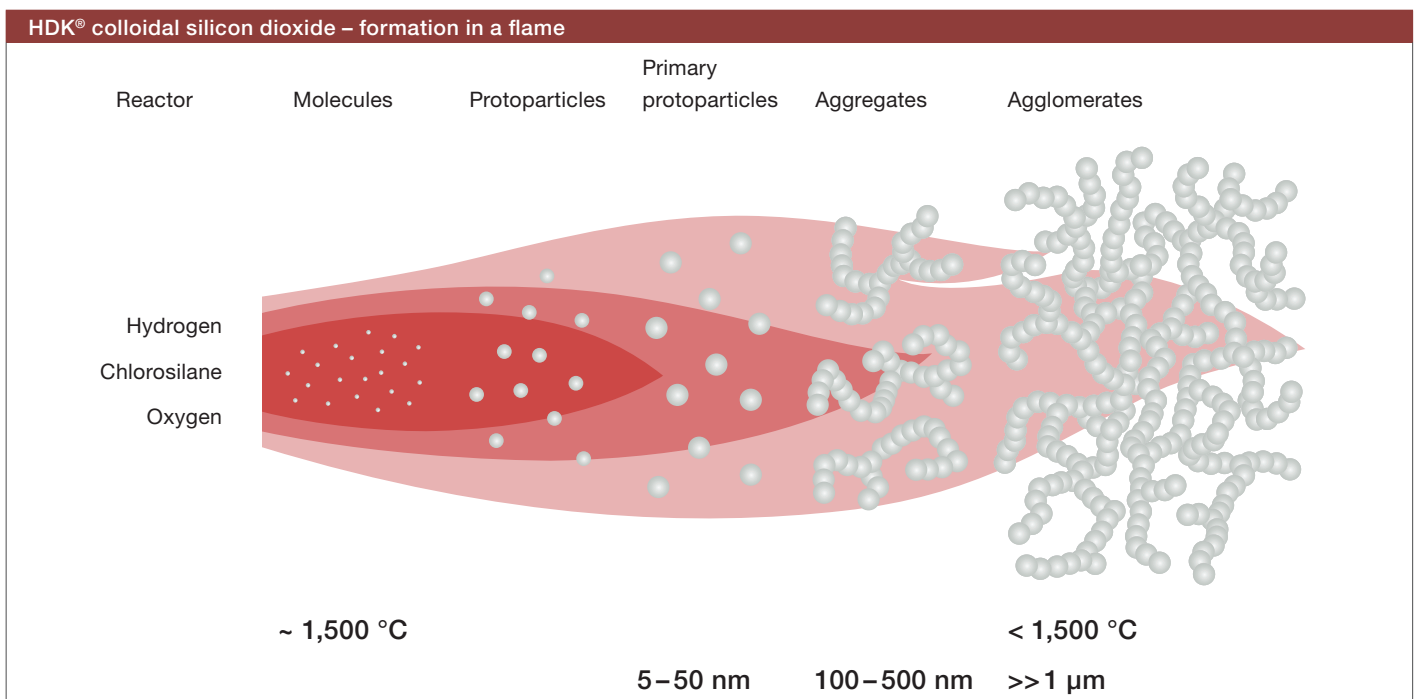
HDK® pyrogenic silica is generated by hydrolysis of chlorosilane in an oxyhydrogen flame at temperatures above 1,200 °C. Initially, round SiO₂ primary particles about 5 – 50 nanometers in size are formed. In the flame, the primary particles fuse together permanently to form aggregates (100 – 1,000 nm in size). On cooling, the aggregates mechanically entangle to form even larger agglomerates (several microns in size). These are obtained as a white, odorless HDK® powder.

When obtained by the flame process, HDK® is extremely pure. It has a highly branched morphology and its surface is rich in silanol groups. The silica's large specific surface area enables strong particle interactions. These are the key factors for its use as a pharmaceutical excipient and food additive, primarily for free flow and rheology control.

TIP

Thanks to our many years of experience, we have the expertise to provide you with a very high level of application support and can offer you specific products that exactly match your application requirements.

- 50 years of production history
- Integrated production system
- Uses only the highest-quality, internally sourced raw materials
- Flame process allows exceptional HDK® purity



CONSISTENCY AND PURITY

Regular Analysis for Reliable Product Quality

Typical analytical data of HDK®

Elemental impurities as listed in the ICH's "Q3D Guideline for Elemental Impurities"

| Element | Measured level [ppm] | Element | Measured level [ppm] |
|---------|----------------------|---------|----------------------|
| Cd | < 0.5 | Rh | < 1 |
| Pb | < 0.5 | Ru | < 1 |
| As | < 1 | Se | < 1 |
| Hg | < 1 | Ag | < 1 |
| Co | < 1 | Pt | < 1 |
| V | < 1 | Li | < 1 |
| Ni | < 1 | Sb | < 1 |
| Tl | < 1 | Ba | < 1 |
| Au | < 1 | Mo | < 1 |
| Pd | < 1 | Cu | < 1 |
| Ir | < 1 | Sn | < 1 |
| Os | < 1 | Cr | < 1 |

The figures are only intended as a guide and should not be used in preparing specifications.

Typical General Properties:

Appearance: fluffy white powder
Solid structure of SiO₂: 100% amorphous
Refractive index: 1.46
Tamped density: approx 40 g/l (non-pressed) or 100 g/l (pressed)
Loss on ignition (2 hours at 1,000 °C): < 2%
SiO₂ content: > 99.8%

Analytical Methods for Elements:

- Flame AES and ICP
- "<" indicates the detection limit has been reached

HDK® GRADES, PHARMA

An Excellent Excipient to Improve Product Quality



In Tablets, Capsules and Powders

HDK® PHARMA is perfectly suited to improving and maintaining the free flow of powders. If standard mixing equipment is used, the silica particles can be evenly distributed over the host particles' surfaces. The HDK® particles act as spacers and reduce the interparticle forces.

Consequently, the powder free flow will be improved and the formation of lumps during storage is avoided.

- Glidant for tablets, capsules and powders
- Facilitates tablet compression by reducing particle interaction
- Helps to enhance production processes wherever it is necessary to convey powders smoothly
- Adsorbs moisture from hygroscopic materials
- Adsorbs liquids; can convert liquids into powders, the conversion being determined by the loading level
- Reduces incompatibility between different components of a preparation
- Supports even distribution of ingredients in powder formulations
- Improves disintegration when tablets dissolve



In Pharmaceutical Liquids

In liquids, HDK® PHARMA particles show a shear-dependent viscosity build. Liquid formulations can be thickened to obtain a rich-bodied cream, but are rendered shear thinning to facilitate application and provide good feel. Optimum performance requires the silica to be well dispersed using appropriate high-shear devices.

- Rheology additive for liquid formulations like gels, creams and suspensions
- Prevents hard settling, sedimentation and striation
- Improves gel clarity
- Improves uniformity of raw-material distribution
- Improves ease of gel/cream application
- Enhances suspension and prevents settling in aerosols



HDK® GRADES, NUTRITION

Direct Food and Feed Additive for Free Flow and Thickening



HDK® NUTRITION is a highly pure and consistent food additive. It improves the flow of food powders and provides precise rheology control in liquid food products. HDK® NUTRITION is available for the most demanding of free-flow applications.

- Excellent free-flow additive for food powders, including soft organic powders
- Maintains a lump-free and dry powder quality during storage
- High moisture-adsorption capability, works well with humid or hygroscopic powders
- Suitable for thickening marinades, oils and other liquid food products
- Thixotropic agent for oil-based baking and cooking sprays

TIP

HDK® NUTRITION also helps optimize your processes, for example by increasing the cleanliness of your equipment during the milling and grinding of raw materials.



HDK® in Feed Products

HDK® NUTRITION is a valuable additive for enhancing not only the properties but also the processing of your feed products. It ensures free flow and good storage properties in supplement powders as well as accurate moisture regulation in pellets. It can also optimize processes like milling or grinding by preventing the products from caking and adhering to the process equipment.



HDK® – CERTIFIED QUALITY

We Ensure Safety and Compliance

Pharmaceutical Regulations

HDK® PHARMA grades meet the purity requirements given in the corresponding monographs “Silica, Colloidal Anhydrous” under the current version of the European Pharmacopoeia and “Colloidal Silicon Dioxide” under the current version of the US Pharmacopeia and “Colloidal silicon dioxide” of the British Pharmacopoeia.

HDK® PHARMA grades meet the description of “Light Anhydrous Silicic Acid (sic)” in the monograph of the current version of the Japanese Pharmacopoeia.

HDK® PHARMA grades are fully registered in a US Type IV Drug Master File.

HDK® PHARMA grades comply with Title 21, Code of Federal Regulations, Section 314.420, as interpreted in the “Guidelines for Drug Master Files” (HEW FDAO 79-3072). The HDK® production sites operate under ISO 9001 and ISO 14001 certificates.



Food Regulations

HDK® NUTRITION grades are suitable for use as a direct food additive in accordance with Annexes II and III of Regulation (EC) No 1333/2008 as amended by Regulations (EU) No 1129/2011 and 1130/2011. They meet the specifications for E 551 under (EU) No. 231/2012 and for INS 551 according to the current JECFA and FCC monographs.

HDK® PHARMA and NUTRITION grades are in accordance with Regulation (EU) 10/2011 (Ref. No. 86240) as an indirect food additive in plastic food-contact materials. Wacker Chemie's HDK® production site in Nünchritz is a registered food and feed producer under German law. Production, packaging and storage facilities for HDK® PHARMA and NUTRITION are HACCP-certified.

HDK® PHARMA and NUTRITION grades are certified under halal and kosher regulations.



Please refer to our Regulatory Information Sheet.

PACKAGING

Convenient and Functional



Pallets of Paper Bags

HDK® is available in multilayer valved paper bags which contain different product volumes. The bags are delivered on pallets which are shrink-wrapped with a tamper-proof polyethylene film to protect the HDK® against moisture. This allows the product to be stored without any moisture uptake. If the shrink film is damaged or single bags are removed, care must be taken to protect the remaining bags/individual bags against moisture by either wrapping them in plastic or by taking other appropriate measures.

- Palletized and shrink-wrapped for good product protection, storage and handling
- Three-ply paper for added strength
- Bags are disposable
- Tamper-proof packaging

PERSONAL SUPPORT INCLUDED

We Are Here to Help You Get Perfect Results

Our HDK® team gives you access to qualified experts you can approach directly. We foster a culture based on many years of expertise and long-term business partnerships to ensure continuity. Our highly qualified experts support you by adopting an all-encompassing approach that takes account of the different factors decisive for your success.

Technological Factors

Many factors are involved in selecting the right grade of HDK® for the best performance. The composition of your product, its manufacturing method, application, substrate, and target properties must all be taken into consideration. Our support package includes technical recommendations, studies in our labs, and lab or production trials at your plant. To achieve all this, we have 60 years of expertise in silica and highly qualified experts.

A Local Presence and a Common Language

We support you with our technical service and WACKER Academy training centers in your region. We have staff located in your region and time zone, speaking your language.

Regulatory Compliance

At WACKER, our first priority is to ensure the safety of patients and consumers. Consistent product quality, exceptional purity and innocuous raw materials are of paramount importance to us. HDK® is compliant with major substance inventories worldwide. This includes registrations under Regulation (EC) No. 1907/2006 (REACH), covering the supply of HDK® to the European Economic Area by Wacker Chemie AG and its affiliates.

TIP

Wherever you are, you're able to reach a trained expert to help you with your problem.



EXPERTISE AND SERVICE NETWORK ON FIVE CONTINENTS



WACKER is one of the world's leading and most research-intensive chemical companies, with total sales of €4.91 billion. Products range from silicones, binders and polymer additives for diverse industrial sectors to bio-engineered pharmaceutical actives and hyperpure silicon for semiconductor and solar applications. As a technology leader focusing on sustainability, WACKER promotes products and ideas that offer a high value-added potential to ensure that current and future generations enjoy a better quality of life based on energy efficiency and protection of the climate and environment. Spanning

the globe with five business divisions, operating 25 production sites, WACKER is currently active in over 100 countries. The Group maintains subsidiaries and sales offices in 29 countries across Europe, the Americas and Asia – including a solidly established presence in China. With a workforce of 17,200, WACKER sees itself as a reliable innovation partner that develops trailblazing solutions for, and in collaboration with, its customers. WACKER also helps them boost their own success. Our technical centers employ local specialists who assist customers worldwide in the development of products

tailored to regional demands, supporting them during every stage of their complex production processes, if required. WACKER e-solutions are online services provided via our customer portal and as integrated process solutions. Our customers and business partners thus benefit from comprehensive information and reliable service to enable projects and orders to be handled fast, reliably and highly efficiently. Visit us anywhere, anytime around the world at: **www.wacker.com**

All figures are based on fiscal 2011.

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