

## HI-SIL<sup>®</sup>, LO-VEL<sup>®</sup> and SILENE<sup>™</sup> Precipitated Silicas

This information sheet refers to the following Qemetica untreated precipitated silica products: HI-SIL<sup>®</sup> silica: All grades; the following untreated LO-VEL<sup>®</sup> grades: *Lo-Vel* 27, *Lo-Vel* 29, *Lo-Vel* 39A, *Lo-Vel* 275, *Lo-Vel* 2000, *Lo-Vel* 2003, *Lo-Vel* 6000, *Lo-Vel* 6200, and *Lo-Vel* HSF silicas; and SILENE<sup>™</sup> 732D silica. These untreated *Hi-Sil*, *Lo-Vel*, and *Silene* precipitated silica products are suitable for general use including food contact applications as specified in the applicable USA and European regulations. These products are not recommended for food/feed applications. For food/feed applications, please see the FLO-GARD<sup>™</sup> Silica Global Product Safety and Regulatory Information Sheet.

### General Information

**NAME:**

Precipitated Synthetic Amorphous Silica

**DESCRIPTION:**

Untreated *Hi-Sil*, *Lo-Vel*, and *Silene* silicas are synthetic, hydrated amorphous silicas, covered by CAS REGISTRY NUMBER: 112926-00-8 Synthetic amorphous precipitated silica (polysilicic acid). CAS# 7631-86-9 is used for TSCA inventory purposes. EC Number 231-545-4 is used for EU REACH registration purposes.

**COMPOSITION:**

Regulatory silica is a single substance; it is 100 percent the precipitated Synthetic Amorphous Silica substance. Qualitatively, SiO<sub>2</sub>-Hydrate is the main component, the side products are Sodium salt, (free + bound) water and small traces of metal oxides (e.g., Al<sub>2</sub>O<sub>3</sub>, CaO, Fe<sub>2</sub>O<sub>3</sub>) can be present.

**STORAGE/SHELF LIFE:**

Handling and proper storage is essential to the performance of the product. Silica is hygroscopic and may pick up moisture when stored for a long period of time, even in the best of conditions. Qemetica recommends that silica products be stored under dry, clean conditions and protected against exposure to other substances. Qemetica also recommends that products that are stored more than one year from date of manufacture be re-tested for moisture content since this product may pick up moisture.

### Global Regulatory Information

**CHEMICAL INVENTORY STATUS:**

- United States inventory (TSCA 8b): All components are listed (active) or exempted.
- Australia inventory (AICS): All components are listed or exempted.
- Canada inventory (DSL): All components are listed or exempted.
- China inventory (IECSC): All components are listed or exempted.
- Japan inventory (ENCS): All components are listed or exempted.

- Korea inventory (KECI): All components are listed or exempted.
- New Zealand (NZIoC): All components are listed or exempted.
- Philippines inventory (PICCS): All components are listed or exempted.
- EU REACH registration: QEMETICA has registered the Synthetic Amorphous Silica (SAS) substance (CAS Registry Numbers 7631-86-9 and 112926-00-8; EC-No. 231-545-4) with the European Chemicals Agency in Helsinki (ECHA) in compliance with European “Registration, Evaluation and Authorization of Chemicals” (REACH) Regulation (1907/2006/EC). Our registration supported the manufacture of this substance at Qemetica’s factory in Delfzijl, the Netherlands, and the import from our manufacturing facilities located outside the EU.
- Taiwan inventory (TCSI): All components are listed or exempted.

## United States of America (USA) Regulatory Information

### FDA STATUS

See specific citations for possible limitations on use:

For food contact uses, silicon dioxide is cleared or permitted under:

- 21 CFR 175.105 (Adhesives)
- 21 CFR 177.2420 (Cross-Linked Polyester Resin)
- 21 CFR 177.2600 (Rubber Articles)
- 21 CFR 182.90 (Paper and Paperboard)
- 21 CFR 178.3297 (Indirect Food Additives, Adjuvants, production aids, and sanitizers subpart D- Certain Adjuvants and Production Aids for food contact uses)
- 21 CFR 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods)
- 21 CFR 176.180 (Components of paper and paperboard in contact with dry food)

Silicon dioxide is exempted from the tolerance requirements under:

- 21CFR 182.99 (Adjuvants for Pesticide Chemicals) and is specifically listed as an acceptable inert in pesticide formulations under EPA 40 CFR 180.950 as “silica gel, precipitated, crystalline-free, CAS No. 112926-00-8”

The references above identify the specific clearances in FDA’s regulations for the use of silicon dioxide in food, feed, and food contact applications. Other uses of silicon dioxide in FDA regulated applications also may be acceptable after a review of the proposed use to determine the regulatory status of Qemetica’s product in applications not covered by the regulations identified above, inquiries must be made in writing to [silicacustserv@ppg.com](mailto:silicacustserv@ppg.com). To avoid delays in providing a response, please be as specific as possible in your inquiry, and provide the complete name of the Qemetica product that is subject of your request.

### GOOD MANUFACTURING PRACTICES (GMP)

For silica products used in food and feed applications, Qemetica’s GMPs meet the requirements of FDA’s regulations in 21 C.F.R. Part 117. GMP written procedures include the following elements:

- Regulatory and Internal Inspections;
- Internal Audit Checklist;
- Critical Control Points Monitoring (including HARP-C);
- Critical Control Points Monitoring (including HACCP);

- Finished Product Analysis;
- Sanitary Operations for Housekeeping for Contractors, Maintenance, and Laborers;
- Lubricant/Chemical Storage & Lubricant Equipment List;
- Detailed Cleaning Procedures;
- Temporary Eating and Smoking Areas;
- Sanitary Facilities and Controls (including Pest Controls)

For silica products used in food contact applications, Qemetica's GMPs meet the requirements of FDA's regulations in 21 CFR 117 and, in the EU regulation (EC) 2023/2006.

## REGULATORY AND SPECIFIC PRODUCT INFORMATION

- **Bisphenol A**

Based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to Qemetica by its raw material suppliers, Bisphenol A is not intentionally added to these products and we would not expect Bisphenol A to be present in these products.

- **California Proposition 65**

If applicable, the warning statements appear in Section 15, "REGULATORY INFORMATION" on the product U. S. Safety Data Sheet (SDS). Additionally, the SDS provides information to guide users to minimize exposure.

- **Consumer Product Safety Improvement Act ("CPSIA"), 15 U.S.C. U.S.C. 2087**

Lead and Phthalates are not intentionally added to Qemetica's silica products nor are they expected to be present. Based on our knowledge of the manufacture and handling of the silica products, they would not contain lead in quantities greater than 0.009% or di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DNOP) in quantities greater than 0.1%.

- **HAP Information**

These products do not contain hazardous air pollutants (HAPs) as listed in the Clean Air Act Amendments of 1990, 42 USC 7412(b).

- **Ozone-Depleting Chemicals**

These products do not contain ozone-depleting chemicals as listed in 40 CFR 82, Subpart A, Appendix F.

- **Per- and Poly- Fluoro Alkyl Substances (PFAS)**

Based on our current knowledge of these products and the information provided to Qemetica by its raw material suppliers, Qemetica does not intentionally add and therefore we do not expect these products to contain PFOA (CAS 335-67-1), PFOS (CAS 1763-23-1), PFCA C9-C14, PFAS listed in the US-EPA PFAS chemicals lists (with and without explicit chemical structures), or a non listed substance(s) (e.g. fluoro-silicones) that fits the OECD PFAS definition: <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/aboutpfass/>. Note that the US EPA PFAS Master List has been replaced with 2 separate lists: "PFASSTRUCTV5 - August 2022" and "PFASDEV2 - August 8th 2021": <https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT> and <https://comptox.epa.gov/dashboard/chemical-lists/PFASDEV>

- **RCRA Hazardous Waste Chemical**

To our knowledge, these products, if discarded or spilled, would not be a regulated hazardous waste under 40 CFR 261, but we have not tested them by the Toxicity Characteristic Leaching Procedure. Consult Product Safety Data Sheet (SDS) for additional information.

- **Toxics in Packaging Clearing House (TPCH) (formerly CONEG Regulation / Heavy Materials in Packaging)**

Lead, cadmium, mercury, and hexavalent chromium are not intentionally added to these products and the sum of the incidental concentration levels of these metals does not exceed 100 parts per million (ppm) by weight.

- **Toxic Pollutants/Priority Pollutants**

These products do not contain toxic pollutants / priority pollutants as listed in 40 CFR 401.15.

- **TSCA**

The constituents of these products are not currently subject to any chemical-specific rules or orders under TSCA Sections 4, 5, 6, 7, 8 and are not currently subject to TSCA section 12(b) export notification requirements.

- **VOC Information**

These products do not contain constituents that qualify as volatile organic compounds based on the definition in 40 CFR 51.100.

## European Union (EU) Regulatory Information

### FOOD CONTACT

Our silica products are compliant with EC 1935/2004 which is the Framework Regulation Food Contact Materials have to comply with in Europe.

Synthetic Amorphous Silica is included in Annex I (Union list of authorized monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids) of Regulation EU 10/2011 as amended, under the FCM substance number 504. Qemetica's silica products meet the particle size limitation of "primary particles of 1-100 nm which are aggregated to a size of 0.1 – 1 µm which may form agglomerates within the size distribution of 0.3 µm to the mm size." Through a series of analytical experimentation and theoretical considerations, it can be unambiguously concluded that, once dispersed in a polymeric matrix, precipitated hydrophilic synthetic amorphous silica particles do not leach out when in contact with food. It should be noted that Regulation (EU) 10/2011 does not establish a specific migration limit (SML) for silica; Furthermore, the inclusion of hydrophilic synthetic amorphous silica in plastics does not induce the formation of non-intentionally added substances (NIAS). Therefore, we can conclude that our silica products are compliant with Regulation (EU) 10/2011 as amended.

The applicable regulations, including any national/regional regulations not mentioned in GPSIRS, should be consulted for complete details regarding finished article or surface coatings. Synthetic amorphous silica does not come into contact with foodstuff – it is processed into final articles or coatings intended to come into contact with food. Please note that it is the responsibility of both the manufacturers of food contact materials, surface coatings and articles as well as the industrial food packers, to make sure that these products, in their actual use are in compliance with any imposed requirements.

## REGULATORY AND SPECIFIC PRODUCT INFORMATION

- **End of Life Vehicle (ELV)**

These products have been reviewed with regard to the EU Directive 2000/53/EC. Based on our knowledge of these products and the information on the raw material suppliers' safety data sheets, these products do not contain intentionally added cadmium, hexavalent chromium, lead and mercury.

- **Heavy Metals in Packaging and Packaging Waste**

These products have been reviewed with regard to the EU Directive 94/62/EC. Based on our knowledge of these products and the information on the raw material suppliers' safety data sheets, these products do not contain intentionally added lead, cadmium, mercury, or hexavalent chromium and the incidental concentration level of each of these metals does not exceed 100 parts per million (ppm) by weight.

- **Microplastics**

According to EU regulation 2023/2055 amending Annex XVII to regulation (EC) 1907/2006 (REACH), "microplastics" are defined as solid synthetic polymer (containing) microparticles with carbon atoms in their chemical structure, which are not biodegradable and not soluble. Synthetic Amorphous Silica is an inorganic, carbon-free single substance and thus out of scope of Annex XVII on restrictions of intentionally added microplastics.

- **Per- and Poly- Fluoro Alkyl Substances (PFAS)**

See OECD under US regulations above on page 3.

- **Phthalates**

These products have been reviewed with regard to REACH 907/2006/EC Annex XVII and based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to Qemetica by its raw material suppliers, bis (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), di-"isononyl" phthalate (DINP), di-"isodecyl" phthalate (DIDP), and di-n-octyl phthalate (DNOP) are not intentionally added to these products and we would not expect these substances to be present in the products.

- **RoHS/WEEE**

These products have been reviewed with regard to the EU Directive 2011/65/EC "Restriction on the Use of Certain Hazardous Substances" (RoHS). Based on our knowledge of these products and the information on the raw material suppliers' safety data sheets, these products do not contain cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBBs) or polybrominated diphenyl ethers (PBDEs), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP) at levels greater than the tolerated maximum concentration values established by the EU Commission Decision 2011/65/EC and amendment (EU) 2015/863 (RoHS 3).

- **Substances of Very High Concern (SVHC)**

We routinely review these products with regard to the substances included in the most recent SVHC candidate list and based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to Qemetica by its raw material suppliers, these products do not contain any of the substances included in the Candidate List at levels greater than the tolerated maximum concentration values established by the EU Regulation 1907/2006/EC, or above 0.1%, whichever is lower.

- **VOC Information**

These products do not contain constituents that qualify as volatile organic compounds based on the definitions in EU Directives 2010/75/EU, Industrial Emissions Directive and 2004/42/EC, Paint Products Directive.

### **Other Regulatory Information (outside US and EU)**

- **Chinese Food and Food Contact Regulations**

- GB 9685-2016: Table A1 (Food Contact Plastics)
- GB 9685-2016: Table A2 (Food Contact Coatings and Coating Layers)
- GB 9685-2016: Table A3 (Food Contact Rubbers)
- GB 9685-2016: Table A4 (Food Contact Inks)
- GB 9685-2016: Table A5 (Food Contact Adhesives)
- GB 9685-2016: Table A6 (Food Contact Papers and Paperboards)

Our silica products are compliant with these regulations.

- **Japan Positive List for Food Contact Materials**

The Japanese Ministry of Health, Labor, and Welfare amended Notification No. 370 to provide for Positive List (PL) of the components used in contact with food. See: MHLW Notification No. 195 and No. 196 of 2020. The PL System took effect on June 1, 2020. This means that additives and coating agents used for food-contact will need to be on the new Japanese PL System. Synthetic Amorphous Silica (CAS-No. 112926-00-8) is present on Table 2: Additives and coating agents, No.378 with the remark it can be applied at not more than 600 mg/m<sup>2</sup>.

- **Mercosur Food and Food Contact Regulations**

- GMC/RES No 68/00: Technical Regulation on Synthetic Casings of Regenerated Cellulose
- GMC/RES No 40/15: Technical Regulation on Cellulosic materials, packaging and equipment intended to come into contact with food
- GMC/RES No 42/15: Technical Regulation on Cellulosic Materials, Packaging and Equipment intended to be in contact with food during cooking or baking
- GMC/RES No 39/19: Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coatings in contact with food
- GMC/RES No 41/15: Technical Regulation on Cellulosic materials for cooking and hot filtration

Our silica products are compliant with these regulations.

- **Swiss Ordinance (RS 817.023.21)**

Silicon dioxide is listed in Annex 10 of the Swiss Ordinance on Materials and Articles In Contact with Food issued by the FDHA on 1 February 2024.

### **Certifications and Listings**

#### **CERTIFICATIONS**

Qemetica Certifications are available [here](#).

- **Quality Management System**

These products are designed, developed, and manufactured in accordance with ISO 9001 standards.



## Additional Product Information

- **Source** These products are derived from mineral and synthetic sources and have not been derived from a plant, animal, petroleum, or fermentation source.
- **Processing / Manufacturing** Water is the only solvent used in our manufacturing process. No post treatment is applied to these products. Sewage sludge, ionizing radiation and pesticides are not used in the manufacturing process.
- Because our silica products are synthetic (see source and processing above), the following items are applicable:
  - **Bovine Spongiform Encephalopathy** These products are not of animal origin, and, to the best of our knowledge, do not contribute to Transmissible Spongiform Encephalopathy (TSE) / Bovine Spongiform Encephalopathy (BSE).
  - **Genetically Modified Organisms (GMOs)/Bio-engineered (BE)** *Hi-Sil* silica products are not manufactured with and do not contain genetically modified organisms.
  - **Natural Latex Rubber** These products are not manufactured with and do not contain natural latex rubber, a material defined in 21 CFR 801.437 (b)(1).
- **Melamine**

Based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to Qemetica by its raw material suppliers melamine is not intentionally added to these products and we would not expect Melamine to be present in these products.
- **Mineral Oil Hydrocarbons (MOH)**

Mineral Oil Hydrocarbons (MOH) – including Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH) – are not intentionally added to this product and we would not expect these substances to be present in this product
- **Partially Hydrogenated Oils (PHO)**

Partially Hydrogenated Oils (PHO) are not intentionally added to these products and we would not expect these substances to be present in these products.

## LISTINGS

### FOOD ALLERGENS

- *Hi-Sil*, untreated *Lo-Vel*, and *Silene* silica products are not manufactured with and do not contain allergens. Qemetica has a documented allergen management plan in place to prevent allergen cross- contamination.
- **ALBA list and Allergens** (as identified by the U.S. Food and Drug Administration in Compliance Policy Guide), **Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens, Issued: 04/19/2001**. Allergens listed in this policy are not intentionally added to the products and we would not expect them to be present in these products.

- **Australia New Zealand Food Standards Code (Labeling)**  
Peanuts, tree nuts, soy, milk, egg, cereals, seafood, fish sesame or derivatives and sulfites (in concentration  $\geq 10$  ppm) are not intentionally added to the products and we would not expect them to be present in these products.
- **Australia New Zealand Food Standards Code (Labeling)**  
Peanuts, tree nuts, soy, milk, egg, cereals, seafood, fish sesame or derivatives and sulfites (in concentration  $\geq 10$  ppm) are not intentionally added to the products and we would not expect them to be present in these products.
- **Canada Gazette, PART II (CGII) Food Allergen Labeling Requirements - August 4, 2012**  
Eggs, milk, mustard, peanuts, seafood (fish, crustaceans, shell fish), sesame, soy, sulfites, tree nuts, and wheat are not intentionally added to the products and we would not expect them to be present in these products.
- **CODEX Labeling of Prepackaged Foods (CODEX STAN 1-1985)**  
Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these; Crustacea and products of these; Eggs and egg products; Fish and fish products; Peanuts, soy beans and products of these; Milk and milk products (lactose included); Tree nuts and nut products; and Sulphite in concentrations of 10 mg/kg or more are not intentionally added to the products and we would not expect them to be present in these products.
- **Commission Delegated Regulation (EU) No 78/2014 (Amending Annex II of Regulation 1169/2011/EC).**  
Allergens listed in this policy are not intentionally added to the products and we would not expect them to be present in these products.
- **Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)**  
Milk, eggs, fish, crustacean shellfish, tree nuts, sesame, peanuts, wheat, gluten and soybeans are not intentionally added to the products and we would not expect them to be present in these products.

## Corporate Responsibility / Policies

### INTEGRATED POLICIES FOR QEMETICA

The Management Board of QEMETICA S.A. affirms its commitment to supporting all stakeholders involved in the effectiveness of the Integrated Management System. It pledges to provide the necessary resources and means to achieve strategic objectives. This policy serves as a foundation for setting goals and guiding development across QEMETICA Group companies.

For more information on Integrated Policies for QEMETICA:

<https://qemetica.com/uploads/pl/dokumenty/en/integrated-policies-for-qemetica.pdf>

### CORPORATE POLICIES

Additional Qemetica Policies and Practices regarding how Qemetica engages employees, ethics and compliance training, Human rights, Corporate Reporting Incident Rate, Employee Engagement and Development can be found at the following sites:

- Qemetica Code of Conduct: <https://qemetica.com/uploads/en/documents/qemetica-code-of-conduct.pdf>



- **Anti-Fraud and Anti-Corruption Policy of the QEMETICA Group:** The QEMETICA Group enforces a zero-tolerance policy towards fraud and corruption, promoting ethical conduct and legal compliance across all operations. The policy applies to all employees and stakeholders, requiring adherence to anti-corruption laws, internal procedures, and ethical standards. It outlines prohibited behaviors such as bribery, nepotism, and influence peddling, and sets strict rules for offering and accepting gifts. The Group mandates regular training, transparent reporting mechanisms, and disciplinary actions for violations. The policy also includes contractual clauses to ensure compliance among business partners.

For more information on Anti-Fraud and Anti-Corruption Policy of the QEMETICA Group, please visit:

<https://qemetica.com/uploads/pl/dokumenty/en/anti-fraud-and-anti-corruption-policy-of-the-ciech-group.pdf>

- **Conflict Minerals**

QEMETICA is aware of Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the Securities and Exchange Commission's (SEC) final rules requiring QEMETICA to publicly disclose its use of certain conflict minerals.

QEMETICA hereby inform, that Tantalum, tin, tungsten, and gold are not intentionally added to these products.

- **The California Transparency in Supply Chains Act of 2010:**

In January of 2012, the State of California enacted legislation (The California Transparency in Supply Chains Act of 2010 – S.B. 657) that requires retailers and manufacturers doing business in California to disclose their efforts to combat slavery and human trafficking, and to eliminate it from their direct supply chains.

## SECURITY

- Qemetica professionals develop, implement and audit the corporation's global security policies. In compliance with Qemetica Corporate Policy, each Qemetica facility has established procedures to control access of employees, contractors, customers, other visitors and vehicles to the site while restricting access of unauthorized personnel. These procedures help to assure Qemetica's ability to control who and what enters Qemetica facilities and have a record at any given time of who is on the premises. In addition, Qemetica conducts background checks on all of its employees and provides guidelines for contractors to conduct background checks on all of its employees who will be assigned to Qemetica facilities. Initial and random drug screening of employees also helps to protect the integrity of Qemetica products. Qemetica monitors local and specific threats via communication with governmental organizations such as the FBI and Coast Guard and Industry groups such as the Overseas Advisory Council (OSAC) and the American Chemistry Council (ACC). Qemetica maintains relationships with government law enforcement agencies, wherever it does business, to cooperate with them and to share information that best serves all constituents.

## References

**QEMETICA WEBSITE** [www.qemetica.com](http://www.qemetica.com)

Contact Information: For specific inquiries, please contact your Qemetica sales or customer service representative at:

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