

PPG HI-SIL[®], LO-VEL[®] and SILENE[™] Precipitated Silicas

This information sheet refers to the following PPG untreated precipitated silica products: PPG HI-SIL[®] silica: All grades; the following untreated PPG LO-VEL[®] 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 PPG SILENE[™] 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 PPG FLO-GARD[™] 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 (CAS# 7631-86-9 for TSCA inventory purposes) – Synthetic amorphous precipitated silica (polysilicic acid), EC Number 231-545-4.

COMPOSITION:

Regulatory silica is a single substance; it is 100 percent the precipitated Synthetic Amorphous Silica substance. Qualitatively, SiO₂-Hydrate is the main component, the side products are Sodium salt, (free + bound) water and small traces of metal oxides (e.g., Al₂O₃, CaO, Fe₂O₃) 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. PPG recommends that silica products be stored under dry, clean conditions and protected against exposure to other substances. PPG 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: PPG 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 PPG’s factory in Delfzijl, the Netherlands, and through PPG’s appointed Only Representative, PPG Europe B.V., 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 PPG’s product in applications not covered by the regulations identified above, inquiries must be made in writing to 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 PPG product that is subject of your request.

GOOD MANUFACTURING PRACTICES (GMP)

For silica products used in food and feed applications, PPG'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, PPG'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

- **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 PPG'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%.

- **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.

- **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.

- **VOC Information**
These products do not contain constituents that qualify as volatile organic compounds based on the definition in 40 CFR 51.100.
- **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.
- **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.
- **Bisphenol A**
Based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to PPG 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.
- **Melamine**
Based on our current knowledge of these products and the information (such as safety data sheets [SDSs]) provided to PPG 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.
- **Partially Hydrogenated Oils (PHO)**
Partially Hydrogenated Oils (PHO) are not intentionally added to this product and we would not expect these substances to be present in this product.
- **Japan Positive List**
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/m².

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** No post treatment is applied to these products. Sewage sludge, ionizing radiation and pesticides are not used in the manufacturing process.
- Because *Hi-Sil* silica products are synthetic (see source and processing above), the following items are applicable:
 - **Genetically Modified Organisms (GMOs)/Bio-engineered (BE)** *Hi-Sil* silica products are not manufactured with and do not contain genetically modified organisms.
 - **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).
 - **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).

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 EU 10/2011 Amendments 2015/174, 2016/1416 and 2017/752. PPG'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, EU 10/2011 does not establish a specific migration limit (SML) for silica; however, based on the fact that it would not migrate from the polymeric matrix, silica would not exceed the implicit SML of 60 mg/kg for finished products as written in Article 11. 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 EU 10/2011, last amended by EU 2020/1245.

REGULATORY AND SPECIFIC PRODUCT INFORMATION

- **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) at levels greater than the tolerated maximum concentration values established by the EU Commission Decision 2011/65/EC.

- **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.

- **Perfluorooctane Sulfonates and Acids (PFOS/PFOA)**

These products have been reviewed with regard to EU Regulation 2019/1021 under the Stockholm Convention on Persistent Organic Pollutants (POPs), and based on our current knowledge and the information on the raw material suppliers' safety data sheets, these products do not contain perfluorooctane sulfonates (PFOS) or perfluorooctane acids (PFOA) at levels equal or greater than 0,001% by weight.

Note that PFOS/PFOA were originally regulated under EU Directive 76/769/EEC, now replaced by EU Regulation 1907/2006/EC Annex XVII. This entry was removed when PFOS/PFOA became regulated under the POPs Regulation.

- **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 PPG 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.

- **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 PPG 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.

- **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 May 2017.

Certifications and Listings

CERTIFICATIONS

PPG Certifications are available [here](#).

- **Quality Management System**
We maintain certification under ISO 9001 (Lloyd's Register Group Limited is our registrar).
- **NAFTA Status**
NAFTA status and NAFTA Certificates of Origin, where applicable, are available by email request to NAFTA@ppg.com

LISTINGS

FOOD ALLERGENS

- *Hi-Sil*, untreated *Lo-Vel*, and *Silene silica* products are not manufactured with and do not contain allergens. PPG has a documented allergen management plan in place to prevent allergen cross-contamination.
- **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.
- **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.
- **EU Directive 2014/78/EC (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.
- **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.
- **Australia New Zealand Food Standards Code (Labeling)**
Peanuts, tree nuts, soy, milk, egg, cereals, seafood, fish, sesame or derivatives and sulfites (in concentration ≥ 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.

Corporate Responsibility / Policies

CORPORATE RESPONSIBILITY

Our environment, health and safety (EHS) policy provides the guidelines under which we manufacture, market and distribute products globally in a manner that protects our people, neighbors, customers and the environment. The policy incorporates elements from several voluntary global industry initiatives in which we are a participant, including the American Chemistry Council's RESPONSIBLE CARE® program.

For more information on sustainability goals and progress visit: <https://sustainability.ppg.com/>

CORPORATE POLICIES

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

- PPG Ethics, Compliance, and Human Rights:
<https://corporate.ppg.com/Our-Company/Ethics>
- PPG Corporate Sustainability: To fulfill our purpose to Protect and Beautify the World, we are committed to delivering lasting value for all stakeholders. As One PPG, we operate with integrity, work safely, protect the environment for current and future generations, create a diverse, equitable and inclusive workplace, and engage and support the communities where we operate:
<https://sustainability.ppg.com/>
 - PPG Employees and the Workplace:
<https://sustainability.ppg.com/People>
 - PPG Policies Addressing Employee Engagement:
<https://sustainability.ppg.com/People/Engagement>
 - PPG Community Engagement Strategy:
<https://sustainability.ppg.com/community/community-engagement-strategy>
 - Conflict Minerals Sourcing Policy
PPG 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 PPG to publicly disclose its use of certain conflict minerals. PPG has adopted a conflict minerals policy, and on June 2, 2014, PPG filed its initial conflict minerals report with the SEC describing its due diligence efforts. Both of these documents are available at:
<https://sustainability.ppg.com/Governance/conflict-minerals>
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

- PPG professionals develop, implement and audit the corporation's global security policies. In compliance with PPG Corporate Policy, each PPG 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 PPG's ability to control who and what enters PPG facilities and have a record at any given time of who is on the premises.

In addition, PPG 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 PPG facilities. Initial and random drug screening of employees also helps to protect the integrity of PPG products.

PPG 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). PPG 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

PPG SILICA WEBSITE www.ppgsilica.com

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

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Email: silicacustserv@ppg.com

Europe: +31-596-676710
Email: csdelfzijl@ppg.com

Technical Service: (+1) 800-764-7369

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