

Vanilla SilQ HD™ Barium Sulfate for Suspension

Product Code: 256-4496

Manufacturer: Genus Medical Technologies, LLC
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Section 1: Identification

Product Name: Vanilla SilQ HD™ Barium Sulfate for Suspension (High Density)

Recommended Use: For use as a contrast agent in radiographic studies (after reconstitution).

Restrictions on Use: For use only by or under the supervision of a licensed physician. Prescription only contrast media for radiographic studies.

Section 2: Hazard(s) Identification

GHS Classification: This product is **not classified** as hazardous according to the OSHA Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Signal Word: None required

Hazard Statements: None required under GHS criteria.

Precautionary Statements:

- Avoid prolonged or repeated contact with skin and eyes.
- Wash thoroughly with soap and water after handling.
- Use appropriate personal protective equipment (see Section 8).
- For professional medical use only.

Other Hazards: May cause mild mechanical irritation to eyes or skin upon prolonged contact (dust from powder forms or liquid suspension). Not expected to cause sensitization, mutagenicity, carcinogenicity, or reproductive toxicity under normal conditions of use.

Section 3: Composition / Information on Ingredients

The specific identity of some components is proprietary and is considered a trade secret under 29 CFR 1910.1200.

Component	CAS No.	Concentration
Barium Sulfate	7727-43-7	98% w/w
Suspending & dispersing agents	Proprietary	Proprietary Blend
Flavors, sweeteners, preservatives	Proprietary	Proprietary Blend

Note: Barium sulfate is the active radiopaque ingredient. Other components are suspending agents, flavors, and preservatives.

Section 4: First-Aid Measures

Eye Contact: Remove contact lenses if present. Flush immediately with plenty of cool running water for at least 15 minutes. Consult a physician if irritation persists.

Skin Contact: Wash thoroughly with soap and plenty of water. Remove contaminated clothing. Consult a physician if irritation develops or persists.

Inhalation: Move to fresh air. If breathing difficulty occurs, seek medical attention.

Ingestion: This product is intended for oral administration as a contrast agent under medical supervision. If large amounts are accidentally ingested outside of intended use, contact a physician or poison control center.

Most Important Symptoms/Effects: Mild irritation of eyes or skin. No significant acute toxicity expected from incidental exposure.

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media: Use dry chemical powder, water spray, fog, or foam. Do not use water jet on large fires.

Special Protective Equipment: Firefighters should wear self-contained breathing apparatus (SCBA) and full protective clothing when fighting fires involving chemicals.

Specific Hazards: Product is not flammable. Fine dust from powder forms may form explosive mixtures with air if dispersed in high concentrations (though barium sulfate itself has low combustibility).

Section 6: Accidental Release Measures

Personal Precautions: Avoid contact with eyes and skin. Use appropriate PPE. Ensure adequate ventilation. For powder forms, avoid creating dust.

Environmental Precautions: Do not allow product to enter sewers, soil, or waterways. Barium sulfate has low solubility and low environmental mobility.

Methods for Containment and Cleanup: For small spills, absorb liquid with inert material or sweep up powder carefully and place in suitable container for disposal. For large spills, dike area and collect material. Dispose of in accordance with federal, state, and local regulations. Do not dispose in sewer systems.

Section 7: Handling and Storage

Handling: Use only as directed by a licensed physician for radiographic contrast studies. Avoid prolonged skin and eye contact. Do not eat, drink, or smoke while handling. Wash hands thoroughly after handling.

Storage: Store in original closed container in a cool, dry place away from direct sunlight and heat. Avoid freezing (liquid versions) and temperatures above 40°C (104°F). Keep away from ignition sources and incompatible materials.

Incompatibilities: Strong oxidizing agents, strong acids (may release toxic fumes under extreme conditions).

Section 8: Exposure Controls / Personal Protection

Occupational Exposure Limits: Barium sulfate (as total dust) – OSHA PEL: 15 mg/m³ (total dust), 5 mg/m³ (respirable fraction). ACGIH TLV: 10 mg/m³ (inhalable), 5 mg/m³ (respirable). These are nuisance dust limits; the product is not expected to generate significant airborne concentrations during normal use.

Engineering Controls: Use in well-ventilated areas. Eyewash stations and safety showers should be readily accessible. For powder handling, use local exhaust ventilation if dust is generated.

Personal Protective Equipment:

- **Eye/Face Protection:** Safety glasses or goggles recommended when handling to prevent splashes or dust.
- **Skin Protection:** Chemical-resistant gloves (nitrile or similar) recommended for prolonged handling.
- **Respiratory Protection:** Not normally required. Use NIOSH-approved dust mask if significant dust is generated during handling of powder forms.
- **General Hygiene:** Wash hands and face before eating, drinking, or smoking. Remove contaminated clothing and launder before reuse.

Section 9: Physical and Chemical Properties

Appearance	White to off-white powder (for reconstitution into suspension)
Odor	Light vanilla / vanillin odor
pH	Not determined (reconstituted suspension typically near neutral)
Flash Point	Not determined (product is not flammable)
Solubility in Water	Insoluble (barium sulfate is highly insoluble)
Percent Volatile	Not determined
Particle Characteristics (powders)	Micronized powder; specific particle size distribution proprietary (typical for high-purity barium sulfate)

Section 10: Stability and Reactivity

Reactivity: Stable under normal conditions of use, storage, and transport.

Chemical Stability: Stable when stored as recommended.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Conditions to Avoid: Freezing (liquid products), excessive heat (>40°C), and creation of airborne dust (powder products).

Incompatible Materials: Strong acids and strong oxidizing agents (may cause decomposition under extreme conditions).

Hazardous Decomposition Products: None known under normal conditions. Thermal decomposition at very high temperatures may release sulfur oxides and barium compounds.

Section 11: Toxicological Information

Acute Toxicity: Barium sulfate has very low acute oral, dermal, and inhalation toxicity. It is poorly absorbed from the gastrointestinal tract when administered as a suspension. LD50 (oral, rat) for barium sulfate is >15,000 mg/kg (practically non-toxic).

Skin Corrosion/Irritation: May cause mild mechanical irritation with prolonged contact. Not classified as a skin irritant under GHS.

Serious Eye Damage/Irritation: May cause mild mechanical irritation (foreign body sensation). Not classified as an eye irritant under GHS.

Respiratory or Skin Sensitization: Not expected to cause sensitization based on available data.

Germ Cell Mutagenicity / Carcinogenicity / Reproductive Toxicity: Barium sulfate is not classified as mutagenic, carcinogenic, or toxic to reproduction. IARC, NTP, and OSHA do not list it as a carcinogen.

Specific Target Organ Toxicity (STOT): No specific target organ toxicity expected from single or repeated exposure at levels encountered during normal use.

Aspiration Hazard: Not applicable (not a liquid hydrocarbon).

Section 12: Ecological Information

Ecological studies specific to this formulated product have not been conducted. Barium sulfate is a naturally occurring mineral with very low solubility in water. It is not expected to be highly mobile in the environment or to bioaccumulate significantly. No adverse ecological effects are anticipated from normal use and disposal.

Section 13: Disposal Considerations

Dispose of contents and container in accordance with all applicable federal, state, and local environmental regulations. Do not dispose of in sewers, soil, or aquatic environments. Unused product or waste may be disposed of as non-hazardous waste in many jurisdictions, but confirm with local authorities. Empty containers may be recycled or disposed of as general waste after rinsing.

Section 14: Transport Information

UN Number / Proper Shipping Name: Not regulated as a hazardous material or dangerous good for transport by DOT, IATA, or IMDG.

Transport Hazard Class: Not applicable.

Packing Group: Not applicable.

Environmental Hazards: Not a marine pollutant.

Special Precautions: Protect from freezing (liquid products) or excessive heat during transport. Keep containers upright and tightly closed.

Section 15: Regulatory Information

OSHA Hazard Communication: This product is not classified as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200).

TSCA: All components are listed or exempt from the Toxic Substances Control Act inventory.

FDA: This product is regulated by the U.S. Food and Drug Administration as a prescription contrast agent for radiographic studies.

CERCLA / SARA: Barium sulfate is not subject to reporting requirements under CERCLA or SARA Title III (no RQ listed).

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm at levels requiring warning.

Section 16: Other Information

Revision Date: July 16, 2026

Supersedes: Previous versions dated October 2016 (liquid) and March 2016 (powder). This document has been updated for format, clarity, and GHS alignment.

Disclaimer: The information contained in this Safety Data Sheet is based on data available to Genus Medical Technologies, LLC at the time of preparation and is believed to be accurate. However, no warranty, express or implied, is made regarding the accuracy, completeness, or suitability of this information for any particular purpose. Users should make their own determination of suitability for their intended use. This SDS applies only to the product as originally supplied and packaged. It does not cover uses or mixtures with other substances.

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