# Pharmaceutical gelatin

Scope: PHARGEL soft capsule, hard capsule and microencapsulation grades

## 01 Identification

Product identifier: Pharmaceutical gelatin

Grades / scope: PHARGEL soft capsule, hard capsule and microencapsulation grades. Covers the supplied solid material only; excludes flavored blends, preserved liquids and other formulations.

Recommended use: Professional capsule and microencapsulation manufacture. Excipient use and pharmacopoeial compliance must match the agreed grade and supporting quality documents.

Supplier: Shanghai Protide Biotech Co., Ltd.

Address: Room 1001, Building A, Caohejing Center, No. 1520 Gumei Road, Xuhui District, Shanghai, China.

Contact: sales@protidebio.com | www.protidebio.com | +86-21-54265599

Emergency contact: Contact local emergency medical services or a poison center for urgent assistance. Supplier number is for business inquiries; no 24-hour emergency service is represented.

## 02 Hazards Identification

Classification: Available product information does not establish a specific GHS hazard classification for this supplied preparation. No product-specific classification test report has been provided.

Label elements: No hazard pictogram or signal word is assigned on the available information. This does not remove the need for workplace dust and allergen controls.

Other hazards: Organic fines may form combustible dust concentrations in air. Dust may mechanically irritate eyes and the respiratory tract. Dust explosibility parameters have not been determined.

Allergen considerations: Animal-derived proteins may cause allergic responses in susceptible individuals; assess exposure and cross-contact for the supplied grade.

## 03 Composition / Information on Ingredients

Product description: Bovine-derived gelatin; product CAS reference 9000-70-8. A protein biopolymer with variable molecular-weight distribution. This document covers the unblended supplied gelatin, not finished capsules, active ingredients or capsule-process mixtures.

Physical preparation: Light yellow granules. The matching TDS defines the supplied grade and its quality limits; a protein-content minimum is not a complete ingredient percentage breakdown.

Relevant exposure information: Animal-derived proteins may cause allergic responses in susceptible individuals; assess exposure and cross-contact for the supplied grade.

Composition qualification: Confirm any formulation additives, preservation system or intentional carriers with the ordered specification. This document does not cover materially different mixtures.

## 04 First-Aid Measures

Inhalation: Move to fresh air and stop exposure. Seek medical assistance if breathing difficulty or persistent symptoms occur. Rescue personnel should avoid exposure.

Eye contact: Rinse cautiously with clean water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing; obtain medical advice if irritation persists.

Skin contact: Wash with soap and water. Remove contaminated clothing. Obtain medical advice if irritation or an allergic reaction develops.

Ingestion: Rinse mouth. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical advice if unwell or if an allergic reaction is suspected.

Symptoms / treatment: Dust may cause coughing, discomfort or eye irritation. Treat symptomatically. Urgent care is required for breathing difficulty or a severe allergic reaction.

## 05 Fire-Fighting Measures

Suitable media: Water spray, foam, dry chemical or carbon dioxide, selected for the surrounding fire. Avoid a high-pressure jet that could disperse dust.

Specific hazards: Burning organic material may generate carbon monoxide, carbon dioxide and irritating smoke. Airborne fines can present a dust-explosion hazard; do not assume a nonflammable solid has no dust risk.

Protection: Firefighters should wear appropriate protective clothing and self-contained breathing apparatus. Cool exposed containers where safe and contain contaminated runoff.

## 06 Accidental Release Measures

Personal precautions: Restrict access, ventilate the area and control ignition sources. Avoid raising dust. Use the protective measures in Section 8.

Cleanup: Collect gently into suitable closed containers. Use a vacuum suitable for combustible dust where needed; do not use compressed air or uncontrolled dry sweeping.

Environmental measures: Prevent bulk material entering drains or waterways. Keep recovered material intended for disposal separate from food-grade product; follow local waste requirements.

## 07 Handling and Storage

Safe handling: Use clean, dry tools. Reseal opened bags promptly to protect the material from moisture.

Dust and ignition control: Minimize airborne dust and deposits. Use local extraction and suitable collection equipment; avoid dust clouds, sparks and ignition sources.

Storage: Store sealed in a cool, dry place away from direct sunlight, below 25°C.

Food / grade hygiene: Keep the original material protected from contamination. Separate food, feed and other grades. Follow the order specification and do not return contaminated residues to supply.

## 08 Exposure Controls / Personal Protection

Exposure limits: No product-specific occupational exposure limit is provided. Apply the relevant local limits for inhalable and respirable particulate matter and conduct a workplace assessment.

Engineering controls: Provide ventilation or local extraction at dust-generating operations. Prevent deposits on high surfaces and use suitable dust collection and housekeeping controls.

Eye / skin protection: Use safety glasses or goggles where dust exposure is possible, appropriate work clothing and gloves for hygiene or prolonged contact.

Respiratory protection: Where engineering controls do not adequately control airborne dust, select an approved particulate respirator under the applicable workplace respiratory-protection program.

Hygiene: Wash after handling. Avoid eating or drinking in ingredient-handling areas. Control cross-contact with allergens.

## 09 Physical and Chemical Properties

Appearance / physical state: Light yellow granules

Odor: Characteristic of the supplied source material; no quantitative odor threshold is available.

pH: Not specified in the available product information; request the grade-specific test condition.

Solubility: Swells in cold water and dissolves in warm water; behavior depends on temperature and concentration.

Flash point / boiling point / vapor pressure: Not established for the commercial solid preparation. A dry-solid product is not assigned a liquid vapor-pressure test.

Density / melting / decomposition: No preparation-specific numerical density, melting or decomposition test is supplied for safety classification. Do not transfer values from an unrelated pure substance.

Flammability and explosion information: Organic fines can burn or form a combustible dust cloud under suitable conditions. Kst, Pmax, minimum ignition energy and measured dust explosive limits are not supplied.

## 10 Stability and Reactivity

Stability: Expected to remain stable under the stated dry storage and normal handling conditions. Moisture and contamination may impair quality.

Conditions to avoid: Excessive heat, ignition sources, dust clouds, static discharge, moisture and microbial contamination.

Incompatible materials: Avoid strong oxidizing agents. Do not mix with incompatible cleaning chemicals.

Reactions / decomposition: Hazardous polymerization is not expected in normal handling. Fire or thermal decomposition can generate carbon oxides and irritating smoke; product-specific decomposition testing is unavailable.

## 11 Toxicological Information

Exposure routes: Inhalation of dust, eye or skin contact, and accidental ingestion.

Likely effects: Mechanical irritation from dust or particulate contact may occur. Animal-derived proteins may cause allergic responses in susceptible individuals; assess exposure and cross-contact for the supplied grade.

Acute / repeated-dose toxicity: No product-specific LD50, LC50 or repeated-dose test dataset is available for the supplied preparation. Values for unrelated pure substances are not transferred.

CMR / sensitization: No product-specific test data establish carcinogenicity, mutagenicity, reproductive toxicity or a quantified sensitization threshold. Lack of data is not proof of absence.

Aspiration: The material is supplied as a dry solid. No aspiration-hazard test is supplied.

## 12 Ecological Information

Ecotoxicity: No product-specific aquatic toxicity data are available.

Persistence / bioaccumulation: No preparation-specific biodegradation, bioaccumulation or mobility study is supplied. Do not infer a regulatory conclusion from natural origin.

Environmental control: Avoid bulk release. Organic material entering water may increase oxygen demand and contribute to local contamination.

Other endpoints: PBT, vPvB and endocrine-disruption properties have not been assessed for the supplied preparation.

## 13 Disposal Considerations

Product residues: Recover or dispose of through an authorized route in accordance with applicable local requirements. Do not return contaminated recovered material to food supply.

Packaging: Empty and clean packaging where appropriate before authorized recycling. Handle packaging containing residues according to the residue hazard and local rules.

Waste code: Determine the applicable waste code from actual use and contamination; no universal hazardous/nonhazardous waste classification is assigned here.

## 14 Transport Information

UN number / shipping name: No dangerous-goods UN entry is identified on the available information for the unadulterated supplied solid material.

ADR/RID, IMDG, IATA: No dangerous-goods class or packing group is assigned on the available information. Verify the final consignment and any additives, contamination or destination-specific requirements with the carrier.

Environmental hazards: No marine-pollutant designation is established for this preparation.

Precautions: Keep dry and securely packaged. Prevent bag damage, dust release and contamination. Follow applicable food-transport hygiene controls.

Bulk carriage: Not assessed for maritime bulk transport; arrange requirements separately if applicable.

## 15 Regulatory Information

Scope: This SDS describes workplace handling information; it does not authorize a food, feed, cosmetic or pharmaceutical use or establish market access.

Grade-specific requirements: Professional capsule and microencapsulation manufacture. Excipient use and pharmacopoeial compliance must match the agreed grade and supporting quality documents.

Allergen / source information: Animal-derived proteins may cause allergic responses in susceptible individuals; assess exposure and cross-contact for the supplied grade.

Inventories and certifications: No blanket chemical-inventory registration, religious certification or pharmacopoeial compliance is established by this SDS. Obtain the documents for the actual grade and manufacturing site.

Assessment: No preparation-specific chemical safety assessment or complete toxicological dataset is supplied.

## 16 Other Information

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Prepared by: Shanghai Protide Biotech Co., Ltd.

Abbreviations: GHS: Globally Harmonized System; COA: certificate of analysis; TDS: technical data sheet; PBT/vPvB: persistent/bioaccumulative/toxic or very persistent/very bioaccumulative.

Scope and limitations: Describes available safety and handling information for the named dry material. It is not a quality guarantee, test certificate or confirmation that every toxicological endpoint has been measured. Users must assess actual work conditions, final mixtures and applicable requirements.