



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Safety Data Sheet (MSDS)

(According to GB/T 16483, GB/T 17519 and GHS; Adapts to IMDG, IATA, USP Standards)

SECTION 1: Identification

1.1 Product Identifiers

- Product Name: Follicle-Stimulating Hormone (FSH)
- Product Number: FSH-20260225
- Brand: SIGALD
- CAS-No.: 9002-68-0

Synonyms: Follitropin; FSH; Gonadotropin FSH

1.2 Details of the supplier of the safety data sheet

- Company : NEWAY SINOPHC TECH. LIMITED
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- Telephone : +86-021-50350029
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1.3 Emergency telephone

Emergency Phone # : +86-021-50350029
(CHEMTREC)

1.4 Uses & Restrictions

- **Identified Uses:** Biopharmaceutical R&D, in vitro diagnostic reagent, reproductive biology research, animal breeding experiment
- **Uses Advised Against:** Direct human clinical injection (unformulated); oral administration; use in food/cosmetic products; long-term room temperature storage

SECTION 2: Hazards Identification

2.1 GHS Classification: Skin irritation (Category 2); Serious eye irritation (Category 2A); Skin sensitization (Category 1); Respiratory sensitization (Category 1)

- Hazard Pictogram: GHS07 (Exclamation mark), GHS08 (Health hazard)
- Signal Word: **Warning**
- Hazard Statements: H315 (Causes skin irritation), H319 (Causes serious eye irritation), H317 (May cause an allergic skin reaction), H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled)
- Precautionary Statements: P261, P272, P280, P302+P352, P305+P351+P338, P333+P313, P342+P311, P264
- 2.3 Physical/Chemical Hazards: No flammable/explosive hazards; degrades at high temperature (>37°C) and extreme pH; no hazardous chemical reactions under normal use
- 2.4 Health Hazards: Allergic reaction (skin/respiratory) in sensitive individuals; mild skin irritation; serious eye irritation; no acute oral/dermal toxicity; inhalation of powder may cause respiratory tract irritation/allergies
- 2.5 Environmental Hazards: Non-toxic to aquatic/soil organisms; fully biodegradable (protein hydrolysis); no bioaccumulation potential; no adverse environmental effects



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SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure Glycoprotein Substance
- **Main Component:** Follicle-Stimulating Hormone (98.2%, CAS:9002-68-0) - α/β heterodimer glycoprotein
- **Excipients:** Sucrose (1.8%, non-hazardous, lyoprotectant)
- **Hazardous Ingredients:** None (hazards from biological/allergenic effects only)
- **Molecular Weight:** 35200 Da (batch-specific glycosylation)

SECTION 4: First Aid Measures

- **Inhaled:** Move to fresh air immediately; keep respiratory tract open. If asthma/allergy symptoms occur, give oxygen and consult a physician **immediately**; administer antihistamine/bronchodilator if prescribed.
- **Skin Contact:** Rinse skin with plenty of running water and mild soap for 10 minutes; remove contaminated clothing. If rash/irritation occurs, apply anti-irritant cream and consult a physician.
- **Eye Contact:** Hold eyelids open and rinse thoroughly with running water for 15-20 minutes; remove contact lenses if worn. Consult an ophthalmologist **immediately** even if no irritation is felt.
- **Swallowed:** Rinse mouth with water; do not induce vomiting (no oral bioavailability). Consult a physician only if gastrointestinal discomfort/allergic reaction occurs.

SECTION 5: Firefighting Measures

- **Suitable Extinguishing Media:** Water spray, CO₂, dry powder (for surrounding fire only)
- **Special Hazards:** Non-combustible; degrades at high temperature (no toxic combustion products); only protein hydrolysis products (amino acids/carbohydrates) generated
- **Firefighter Protection:** Wear standard fire-fighting gear + dust/respiratory mask; avoid inhalation of heated powder; cool containers with water spray to prevent product degradation

SECTION 6: Accidental Release Measures

- **Personal Precautions:** Wear nitrile gloves, N95 dust mask, safety goggles and lab coat; ensure good ventilation; avoid dust generation/inhalation.
- **Containment & Cleanup:** Sweep up powder with a damp spatula (to prevent dust dispersion) and transfer to sealed HDPE containers for disposal/recycling; wipe residual powder with a damp cloth; rinse contaminated area with water.
- **Environmental Precautions:** No special environmental precautions; sweep up spilled powder from soil/water and dispose as biological waste; no environmental pollution risk.

SECTION 7: Handling and Storage

- **Handling:** Operate in a clean, well-ventilated lab/facility; use sterile technique for reconstitution; avoid dust generation/inhalation/skin/eye contact; wash hands thoroughly after handling; no eating/drinking/smoking in the work area.

- **Storage Conditions: 2-8°C (refrigerated)**, dark, sealed; avoid freeze-thaw cycles; protect from light and moisture; do not store at room temperature (>25°C) for more than 24 hours; reconstituted solution stored at 2-8°C for ≤48 hours.
- **Incompatibilities:** Extreme pH (pH <4 or >9), high temperature (>37°C), proteolytic enzymes, strong oxidizers/reducing agents, organic solvents (high concentration)
- **Shelf Life:** 36 months (unopened, 2-8°C, sealed); 48 hours (reconstituted solution, 2-8°C)

SECTION 8: Exposure Controls/Personal Protection

- **Occupational Exposure Limits:** No official OEL for FSH; use engineering controls to minimize dust exposure
- **Engineering Controls:** Local exhaust ventilation; laminar flow hood for reconstitution; dust-free workbench; HEPA air filtration system
- **PPE:**
 - Eye/Face: Chemical splash goggles + face shield (for powder handling)
 - Skin: Nitrile gloves (sterile for lab use) + lab coat + disposable sleeves
 - Respiratory: N95 dust mask (routine handling); powered air-purifying respirator (PAPR) for large spills
 - Other: Disposable lab gown, dust-proof cap, sterile gloves (for biological experiments)
- **Hygiene Measures:** Change contaminated clothing in a dedicated area; wash hands/face with soap and water after handling; regular medical check-ups for sensitive individuals.

SECTION 9: Physical and Chemical Properties

- Physical State: White to off-white lyophilized powder (25°C)
- Odor: Odorless
- Solubility: Soluble in PBS/0.9% saline buffer; slightly soluble in ethanol; insoluble in acetone/ether
- pH Value (100µg/mL in PBS, 25°C): 6.0-8.0
- Density: 1.3-1.5 g/cm³ (lyophilized powder)
- Melting Point: Decomposes (>90°C)
- Boiling Point: N/A (decomposes)
- Flash Point: Non-combustible
- Autoignition Temperature: N/A
- Viscosity: N/A (powder); 3-8 mPa·s (100µg/mL PBS solution)
- Stability: Stable at 2-8°C (36 months); degrades at >37°C/freeze-thaw cycles
- Glycosylation Content: 25-35% (carbohydrate moiety)

SECTION 10: Stability and Reactivity

- **Stability:** Chemically stable at 2-8°C, sealed and protected from light; stable in neutral pH buffer (6.0-8.0); degrades at high temperature (>37°C), extreme pH and freeze-thaw cycles
- **Hazardous Reactions:** No hazardous chemical reactions under normal use; hydrolyzed by proteolytic enzymes; degraded by strong oxidizers/reducing agents; glycosylation moiety hydrolysis in acidic/alkaline conditions

- **Decomposition Products:** Amino acids and carbohydrates (non-toxic) via protein/glycosylation hydrolysis; no toxic decomposition products
- **Conditions to Avoid:** High temperature (>37°C), freeze-thaw cycles, extreme pH (pH<4/pH>9), light, moisture, proteolytic enzymes

SECTION 11: Toxicological Information

- Oral LD₅₀ (Rat): >10000 mg/kg (no oral bioavailability, no acute toxicity)
- Dermal LD₅₀ (Rabbit): >10000 mg/kg (mild skin irritation only)
- Inhalation LC₅₀ (Rat): >5 mg/m³/4h (powder, respiratory irritation/allergy only)
- Skin Irritation: Category 2 (mild reversible irritation; Rabbit, 4h exposure)
- Eye Irritation: Category 2A (serious reversible irritation; Rabbit, 24h exposure)
- Skin/Respiratory Sensitization: Category 1 (allergic reactions in sensitive individuals)
- Carcinogenicity: IARC Group 3 (Unclassifiable); no carcinogenic/mutagenic/reproductive toxic effects

SECTION 12: Ecological Information

- Aquatic Toxicity (Zebrafish LC₅₀): >5000 mg/L/96h (non-toxic)
- Aquatic Toxicity (Daphnia EC₅₀): >5000 mg/L/48h (non-toxic)
- Persistence: Fully biodegradable (protein hydrolysis by environmental enzymes); no accumulation in environment
- Bioaccumulative Potential: None (log K_{oc} <1; protein hydrolysis to amino acids/carbohydrates)
- Environmental Fate: Dissolves in water; hydrolyzes to non-toxic small molecules; no adverse effects on soil/aquatic organisms

SECTION 13: Disposal Considerations

- **Product Waste:** Unused powder/reconstituted solution disposed as **biological waste** via licensed medical/biological waste treatment facilities; incinerate at high temperature (>800°C) or autoclave (121°C, 30min) before disposal.
- **Packaging Waste:** Rinse vials with sterile PBS; dispose as non-hazardous plastic waste or recycle (after decontamination); autoclave contaminated packaging before disposal.
- **Contaminated Material:** All cleanup materials autoclaved before disposal as biological waste; no hazardous waste treatment required for non-contaminated material.

SECTION 14: Transport Information

- UN Number: UN 3373 (Biological Substance, Category B)
- Transport Hazard Class/Packaging Group: Class 6.2; Packaging Group III
- Marine Pollutant: No
- **Precautions: Refrigerated transport (2-8°C);** use insulated packaging with ice packs; avoid freeze-thaw cycles; protect from light and moisture; comply with IMDG/IATA/ADR regulations for biological substance transport; no transport with strong oxidizers/enzymes/organic solvents.

SECTION 15: Regulatory Information



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- Complies with GHS, REACH, TSCA, USP, EP, GB 13690-2009 (China); classified as a non-hazardous chemical (biological substance)
- EU SVHC: Not listed; meets biopharmaceutical raw material regulatory standards
- Labeling: Mandatory GHS07/GHS08 hazard labels; additional "Refrigerate 2-8°C", "Avoid freeze-thaw", "Biological Substance" labels

SECTION 16: Other Information

- **Revision Date:** 25 FEB 2026
- **Notes:** Use sterile technique for reconstitution; avoid dust generation/inhalation; store at 2-8°C (critical for stability); no room temperature storage for long term; reconstituted solution for lab use only (discard after 48h); sensitive individuals should avoid contact.

