



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
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## Safety Data Sheet (MSDS)

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

**Product Name:** Recombinant Human Growth Hormone (rhGH) **CAS-No.:** 9002-72-6 **Product**

**Number:** rhGH-20260218 **Brand:** SIGALD **Revision Date:** 18 FEB 2026

### SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

#### 1.1 Product Identifiers

- Synonyms: Somatotropin; Recombinant somatotropin; Human growth hormone (recombinant)

#### 1.2 Supplier Details

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

- 1.3 **Emergency telephone:** +86-021-50350029 (CHEMTREC)

#### 1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material for growth hormone deficiency treatment; biomedical research reagent (hormone pharmacology); cell culture supplement.
- Uses Advised Against: Not for direct injection (unformulated); no unapproved industrial/cosmetic/food use; avoid use in growth hormone-allergic individuals and acromegaly patients.

### SECTION 2: Hazards Identification

2.1 **GHS Classification:** Acute oral toxicity, Category 4 (H302); Eye irritation, Category 2 (H319); Skin sensitization, Category 1 (H317)

#### 2.2 GHS Label Elements

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- Hazard Statements: H302 - Harmful if swallowed; H319 - Causes serious eye irritation; H317 - May cause an allergic skin reaction
- Precautionary Statements: P261, P270, P280, P302+P352, P305+P351+P338, P333+P313

**Physical and Chemical Hazards:** No physical/chemical hazards; non-combustible; highly hygroscopic

2.4 **Health Hazards:** Harmful if swallowed; causes serious eye irritation; may trigger allergic skin reactions in sensitive individuals; growth hormone allergy risk; abnormal growth/metabolic disturbance risk if accidental parenteral exposure; increased intracranial pressure risk in susceptible individuals.

2.5 **Environmental Hazards:** Non-toxic to aquatic organisms; fully biodegradable via enzymatic hydrolysis; no environmental pollution risk.

2.6 **Other Hazards:** High hygroscopy (degrades on moisture absorption); no additional hazards identified.

### SECTION 3: Composition/Information on Ingredients

- **Substance / Mixture:** Pure recombinant polypeptide substance
- **Active Component:** Recombinant Human Growth Hormone (CAS:9002-72-6) | Concentration: ≥99.0% | Classification: Acute oral toxicity Cat.4; Eye irritation Cat.2; Skin sensitization Cat.1

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move to fresh air; rest in comfortable breathing position; consult a doctor if cough/chest discomfort persists (monitor for respiratory/allergic reaction).
  - Skin Contact: Rinse skin with running water and mild soap for 10 mins; remove contaminated clothing; consult a doctor if redness/itching/blistering persists (assess for allergic reaction).
  - Eye Contact: Rinse eyes thoroughly with sterile water for 15-20 mins (hold eyelids open); remove contact lenses; **immediately consult an ophthalmologist.**
  - Swallowed: Rinse mouth with water; **do not induce vomiting**; immediately call a poison control center/consult a doctor; monitor for gastrointestinal/allergenic symptoms.
- 4.2 Symptoms:** Nausea/vomiting (ingestion); eye burning/tearing/blurred vision; skin redness/urticaria (allergic reaction); headache/edema (systemic exposure); increased intracranial pressure (rare, susceptible individuals).
- 4.3 Medical Attention:** Symptomatic treatment; no specific antidote; antihistamines/corticosteroids for allergic reactions; ophthalmic care for eye irritation; neurological assessment for intracranial pressure symptoms.
- 4.4 Notes to Physician:** Inform of product composition (recombinant human growth hormone) and exposure route/amount; assess for growth hormone allergy; monitor for metabolic/neurological adverse effects.

## SECTION 5: Firefighting Measures

- 5.1 Extinguishing Media:** Water spray, foam, CO<sub>2</sub>, dry powder (all suitable)
- 5.2 Special Hazards:** Non-combustible; decomposes at >160°C (ambient)/>110°C (vacuum) into non-toxic amino acids; no toxic combustion/decomposition fumes generated.
- 5.3 Firefighter Advice:** Wear standard fire-fighting gear (no SCBA required); cool containers with water spray to prevent moisture absorption/peptide degradation; no toxic fume inhalation risk.

## SECTION 6: Accidental Release Measures

- 6.1 Personal Precautions:** Wear N95 dust mask, chemical safety goggles, nitrile gloves and clean lab coat; operate in low-humidity (RH ≤30%) ventilated area (high hygroscopic risk).
- 6.2 Environmental Precautions:** No special measures needed; spilled peptide is biodegradable by soil/water microorganisms; no environmental pollution.
- 6.3 Clean Up Methods**
- Small Spill: Sweep up with dry clean spatula; transfer to sealed moisture-proof container for reprocessing/disposal (avoid waste of high-value recombinant polypeptide).
  - Large Spill: Contain with anhydrous inert material (anhydrous silica gel); collect into sealed vacuum container; rinse the area with a small amount of anhydrous ethanol (collect rinse for disposal).
- 6.4 Reference:** See Section 13 for disposal details.

## SECTION 7: Handling and Storage

### 7.1 Safe Handling

- Operate in a **Grade A/B low-humidity clean room (RH ≤30%)**; use sterile disposable equipment; avoid dust generation/inhalation and eye contact.
- Do not eat/drink/smoke in the work area; wash hands thoroughly with water after handling; identify growth hormone-allergic personnel before operation.

- Avoid parenteral contact (injection); use double-layer protective gloves for all handling to prevent skin absorption.
- **7.2 Safe Storage**
- Storage Conditions: **Ultra-low temperature (-80°C±5°C)**, dry, dark, vacuum-sealed; secondary packaging with anhydrous desiccant; avoid repeated freeze-thaw cycles.
- Incompatibilities: Water/moisture, strong acids/bases, proteolytic enzymes (trypsin/pepsin), high temperature, heavy metal ions, oxidizing agents.
- Storage Class (TRGS 510): 10 (Toxic Solids, Non-combustible)
- Shelf Life: 48 months (unopened, -80°C vacuum storage); 3 days (2-8°C refrigerated, after opening)
- Storage Segregation: Store separately from water-containing reagents, proteolytic enzymes, food/feed; store in dedicated recombinant protein ultra-low temperature freezer.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national limit; recommended TWA: 0.01 mg/m<sup>3</sup> (inhalable dust)

### 8.2 Exposure Controls

- Engineering Controls: Grade A/B low-humidity clean room (RH ≤30%); local exhaust ventilation (LEV) for dust-generating operations; anhydrous air supply system; positive pressure environment.
- Personal Protective Equipment (PPE)
  - Eye/Face: Chemical safety goggles + face shield (mandatory)
  - Skin: Powder-free nitrile rubber gloves (≥0.18mm, double-layer); disposable sterile clean lab coat; shoe covers; hair net
  - Respiratory: N95/P95 dust mask for routine handling; powered air-purifying respirator (PAPR) for large-scale powder handling
  - Hand: Powder-free nitrile gloves (no latex, double-layer)
- Hygiene: Change all contaminated PPE immediately; perform hand hygiene with sterile water after handling; no direct skin contact with the product.

## SECTION 9: Physical and Chemical Properties

- Physical State: Lyophilized powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: Decomposes (≥160°C ambient; ≥110°C vacuum)
- Boiling Point: N/A (decomposes before boiling)
- Flammability: Non-combustible
- Flash Point: N/A
- Autoignition Temperature: >350°C
- Solubility: Soluble in water (pH 5.5-7.5), dilute phosphate buffer; insoluble in organic solvents (ethanol/hexane/ether)
- Density (25°C): 1.31 g/cm<sup>3</sup>

- Particle Size: 200-300 mesh (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None
- pH Value: 6.0-7.0 (1mg/mL aqueous solution, 25°C)
- Viscosity: N/A (solid); 2-5 mPa·s (10mg/mL aqueous solution)
- Hygroscopy: Very high (absorbs moisture at RH >30%)
- Vapor Pressure (25°C): < 0.01 hPa

## SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable at -80°C vacuum/dry storage; stable at 2-8°C for 3 days (after opening); degrades rapidly at room temperature/moisture.

10.2 **Hazardous Reactions:** No hazardous reactions; hydrolyzes in water/enzymes to non-toxic amino acids; degrades in strong acids/bases/oxidizing agents/heavy metal ions.

10.3 **Conditions to Avoid:** Moisture (RH >30%), high temperature (>25°C), repeated freeze-thaw, strong acids/bases, proteolytic enzymes, heavy metal ions, direct sunlight, oxidizing agents.

10.4 **Incompatible Materials:** Excess water, concentrated HCl/H<sub>2</sub>SO<sub>4</sub>, NaOH/KOH, trypsin/pepsin, papain, copper/iron/zinc ions, hydrogen peroxide, organic solvents.

10.5 **Decomposition Products:** Non-toxic amino acids (no toxic byproducts); no hazardous decomposition products.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) = 3500 mg/kg; Dermal (Rabbit, LD<sub>50</sub>) >5000 mg/kg; Inhalation (Rat, LC<sub>50</sub>) >0.5 mg/m<sup>3</sup> (4h)
- Skin Irritation/Corrosion: No irritation (Rabbit, 24h exposure); may cause allergic sensitization in susceptible individuals.
- Eye Irritation/Damage: Severe irritation (Rabbit, 24h exposure; reversible with treatment).
- Skin/Respiratory Sensitization: Positive (human/animal tests); growth hormone allergy risk (rare).
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test, in vivo micronucleus test).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP; no tumorigenic effects in animal studies.
- Reproductive Toxicity: No adverse reproductive/teratogenic effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation.
- Target Organ Toxicity: Eyes, skin, endocrine system (metabolic disturbance via systemic exposure); central nervous system (increased intracranial pressure, rare); no chronic target organ toxicity.
- Aspiration Hazard: Low (lyophilized powder, low dustiness); no pulmonary toxicity.

## SECTION 12: Ecological Information

12.1 **Toxicity:** Fish (Zebrafish, LC<sub>50</sub>) >1000 mg/L (96h); Daphnia (EC<sub>50</sub>) >1000 mg/L (48h);

Algae (EC<sub>50</sub>) >1000 mg/L (72h); non-toxic to aquatic life.

12.2 **Persistence and Degradability:** Fully biodegradable (100% hydrolysis) by aquatic/soil microorganisms; degradation half-life =



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0.5-2 days (ambient temperature).12.3 **Bioaccumulative Potential:** None (hydrolyzes to amino acids; no bioaccumulation in food chains).12.4 **Mobility in Soil:** High mobility (soluble in soil water at neutral pH); hydrolyzed by soil microorganisms; no leaching risk (non-toxic).12.5 **PBT/vPvB:** Not classified as PBT/vPvB; non-persistent, non-bioaccumulative, non-toxic.12.6 **Other Effects:** No adverse ecological impacts; hydrolyzed amino acids act as soil nutrients; promotes microbial growth.

### SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** High-value waste: reprocess via lyophilization for reuse; Low-value waste: incinerate at >900°C via licensed hazardous waste facilities (non-toxic ash); Aqueous waste: dilute 1:200 and discharge to biological wastewater treatment system (biodegradable).13.2

**Packaging Waste:** Decontaminate with anhydrous ethanol; dry thoroughly; dispose as biohazardous plastic/glass waste; no recycling with non-pharmaceutical packaging.

### SECTION 14: Transport Information

14.1 **UN Number:** ADR/RID/IMDG/IATA: 281114.2 **UN Proper Shipping Name:** Toxic solids, organic, n.o.s. (Recombinant Human Growth Hormone)14.3 **Transport Hazard Class:** 6.1 (Toxic substances)14.4 **Packaging Group:** III14.5 **Environmental Hazards:** IMDG: Marine pollutant (No)14.6 **Special Precautions:** Ultra-low temperature cold chain transport (-80°C±5°C); vacuum-

sealed packaging with anhydrous desiccant; cryogenic dry ice cooler (styrofoam) with temperature monitor; mark "Do Not Thaw/Refreeze" and "Ultra-Low Temperature Storage Only"; avoid temperature fluctuation, collision, moisture, direct sunlight.14.7 **Incompatible Materials:** Avoid transport with water-containing products, proteolytic enzymes, strong acids/bases, heavy metal salts, organic solvents, food/feed.

### SECTION 15: Regulatory Information

#### 15.1 National & International Regulations

- China: CP compliant; Hazardous Chemical Safety Management Regulation (Class 6.1); Pharmaceutical Raw Material Management Regulation (GMP grade); Recombinant Biological Product Regulation.
- International: GHS (Rev.9) Cat.4 Acute oral toxicity; REACH (EU) Registered; TSCA (US) Listed; USP/EP/FDA compliant; FDA-approved for growth hormone deficiency treatment.15.2 **Other:** Comply with local pharmaceutical import/export (recombinant biological product), ultra-low temperature cold chain transport and hazardous chemical regulations; mark for growth hormone allergy risk.

### SECTION 16: Other Information

- This MSDS is based on current scientific research and complies with GB/T 16483, GB/T 17519 and GHS international standards.
- Supplier is not liable for damage caused by improper use, non-ultra-low temperature storage/transport or non-compliance with safety precautions.



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- Pharmaceutical grade Recombinant Human Growth Hormone meets global pharmacopoeia and recombinant biological product standards; for formulated injectable pharmaceutical products only (GMP conditions).
- For further technical/safety information, contact the supplier's recombinant protein R&D/EHS department (ultra-low temperature cold chain guidance provided).

