



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; Adapts to GHS, IMDG, IATA, USP Standards)

SECTION 1: Identification

1.1 Product Identifiers

- Product Name: Insulin (Recombinant Human Insulin)
- Product Number: INS-20260221
- Brand: SIGALD
- CAS-No.: 11061-68-0

Synonyms: Recombinant Human Insulin; Pancreatic Insulin Hormone

1.2 Details of the supplier of the safety data sheet

- Company : NEWAY SINOPHC TECH. LIMITED
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- Telephone : +86-021-50350029
- Fax : +86-021-50350029

1.3 Emergency telephone

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

1.4 Uses & Restrictions

- Identified Uses: Biopharmaceutical R&D, in vitro diagnostic reagent, diabetes research, human insulin drug development
- Uses Advised Against: Direct human clinical injection (unformulated); oral administration; food/cosmetic use; 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 if inhaled)
- Precautionary Statements: P261, P272, P280, P302+P352, P305+P351+P338, P333+P313, P342+P311
- 2.3 Physical/Chemical Hazards: Non-combustible; non-explosive; degrades at >37°C/extreme pH; no hazardous chemical reactions under normal use
- 2.4 Health Hazards: Allergic reactions (skin/respiratory) in sensitive individuals; mild skin irritation; severe eye irritation; no acute oral/dermal toxicity; inhalation of powder causes respiratory irritation
- 2.5 Environmental Hazards: Non-toxic to aquatic/soil organisms; fully biodegradable (protein hydrolysis); no bioaccumulation; no environmental adverse effects

SECTION 3: Composition/Information on Ingredients

- Substance/Mixture: Pure Recombinant Polypeptide Substance



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- Main Component: Insulin (99.6%, CAS:11061-68-0) - 51 amino acid human insulin hormone
- Excipients: Glycine (0.4%, non-hazardous lyoprotectant/stabilizer)
- Hazardous Ingredients: None (hazards from biological/allergenic effects only)
- Molecular Weight: 5807.6 Da

SECTION 4: First Aid Measures

- Inhaled: Move to fresh air immediately; keep airway open. Administer oxygen if shortness of breath occurs; consult a physician **immediately** for allergic symptoms.
- Skin Contact: Rinse skin with plenty of running water/mild soap for 10 minutes; remove contaminated clothing. Apply anti-irritant cream if rash/irritation appears; consult a doctor if symptoms persist.
- 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 non-toxic amino acids from protein hydrolysis
- Firefighter Protection: Wear standard fire-fighting gear + N95 dust mask; avoid inhalation of heated powder; cool containers with water spray to prevent 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 (prevent dust dispersion) and transfer to sealed HDPE containers; wipe residue with a damp cloth; rinse contaminated area with water.
- Environmental Precautions: No special measures; 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, GMP-compliant well-ventilated lab; use sterile technique for reconstitution; avoid dust generation/inhalation/skin/eye contact; wash hands thoroughly after handling; no eating/drinking/smoking in work area.
- Storage Conditions: **2-8°C (refrigerated)**, dark, sealed; protect from light/moisture; avoid freeze-thaw cycles; do not store at room temperature (>25°C) for more than 24h; reconstituted solution stored at 2-8°C for ≤72h.
- Incompatibilities: Extreme pH (pH<5/pH>9), high temperature (>37°C), proteolytic enzymes, strong oxidizers/reducing agents, heavy metal ions



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- Shelf Life: 36 months (unopened, 2-8°C); 72 hours (reconstituted 1mg/mL PBS solution, 2-8°C)

SECTION 8: Exposure Controls/Personal Protection

- Occupational Exposure Limits: No official OEL for Insulin; minimize dust exposure via engineering controls
- Engineering Controls: Local exhaust ventilation; Class 100 laminar flow hood for reconstitution; dust-free GMP workbench; HEPA air filtration system
- PPE:
 - Eye/Face: Chemical splash goggles + face shield (powder handling)
 - Skin: Sterile nitrile gloves + GMP lab coat + disposable sleeves
 - Respiratory: N95 dust mask (routine handling); PAPR for large spills/bulk processing
 - Other: Disposable GMP gown, dust-proof cap, sterile gloves (biological experiments)
- Hygiene Measures: Change contaminated clothing in a dedicated GMP area; wash hands/face with sterile soap and water after handling; regular medical check-ups for sensitive individuals.

SECTION 9: Physical and Chemical Properties

- Physical State: White lyophilized powder (25°C)
- Odor: Odorless
- Solubility: Soluble in PBS/neutral buffer (pH6.5-7.5); slightly soluble in water; insoluble in organic solvents
- pH Value (1mg/mL in PBS, 25°C): 6.5-7.5
- Density: 1.2-1.4 g/cm³ (lyophilized powder)
- Melting Point: Decomposes (>90°C)
- Boiling Point: N/A (decomposition)
- Flash Point: Non-combustible
- Autoignition Temperature: N/A
- Viscosity: 4-7 mPa·s (1mg/mL PBS solution)
- Isoelectric Point: 5.4 (theoretical)
- Hygroscopy: Slight (absorbs moisture in high humidity)
- Flammability: Non-combustible

SECTION 10: Stability and Reactivity

- Stability: Chemically stable at 2-8°C (sealed/protected from light); stable in neutral buffer (pH6.5-7.5); degrades at >37°C, extreme pH and freeze-thaw cycles
- Hazardous Reactions: No hazardous reactions under normal use; hydrolyzed by proteolytic enzymes; degraded by strong oxidizers/reducing agents; forms aggregates in high temperature/alkaline conditions
- Decomposition Products: Non-toxic amino acids (peptide bond hydrolysis); no toxic decomposition products

- Conditions to Avoid: High temperature (>37°C), freeze-thaw cycles, extreme pH, light, moisture, proteolytic enzymes, heavy metal ions

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)
- Eye Irritation: Category 2A (serious reversible irritation)
- Skin/Respiratory Sensitization: Category 1 (allergic reactions in sensitive individuals)
- Carcinogenicity: IARC Group 3 (Unclassifiable); no 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 environmental accumulation
- Bioaccumulative Potential: None (log K_{oc} <1; hydrolyzes to amino acids)
- Environmental Fate: Dissolves in water; hydrolyzes to non-toxic amino acids; no adverse effects on soil/aquatic organisms

SECTION 13: Disposal Considerations

- Product Waste: Dispose as **biological waste** via licensed medical/biological waste treatment facilities; autoclave (121°C, 30min) or incinerate (>800°C) before disposal.
- Packaging Waste: Rinse vials with sterile PBS; decontaminate and recycle or dispose as non-hazardous plastic waste; autoclave contaminated packaging.
- Contaminated Material: Autoclave all cleanup materials before disposal as biological waste; non-contaminated material disposed as ordinary GMP lab waste.

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 GMP-compliant packaging with ice packs; avoid freeze-thaw cycles/light/moisture; comply with IMDG/IATA/ADR regulations; do not transport with strong oxidizers/enzymes/heavy metal compounds.

SECTION 15: Regulatory Information

- Complies with GHS, REACH, TSCA, USP, EP, ICH Q7, GB 13690-2009 (China); classified as non-hazardous chemical (biological substance)
- EU SVHC: Not listed; meets biopharmaceutical raw material regulatory standards for human drug development



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- Labeling: Mandatory GHS07/GHS08 hazard labels; additional "Refrigerate 2-8°C", "Avoid freeze-thaw", "Biological Substance", "GMP Grade" labels

SECTION 16: Other Information

- Revision Date: 21 FEB 2026
- Notes: Use sterile GMP technique for reconstitution; avoid dust generation/inhalation; 2-8°C storage is critical for stability; reconstituted solution for lab use only (discard after 72h); sensitive individuals should avoid contact; amino acid sequence conforms to native human insulin.

