



# 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 Glargine
- Product Number: INS-20260216
- Brand: SIGALD
- CAS-No.: 113102-64-0

Synonyms: Long-Acting Insulin Analogue; Recombinant Glargine Insulin

#### 1.2 Details of the supplier of the safety data sheet

- Company : NEWAY SINOPHC TECH. LIMITED
- 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

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

#### 1.4 Uses & Restrictions

- **Identified Uses:** Biopharmaceutical R&D, in vitro diagnostic reagent, diabetes research, long-acting 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)2.2 GHS Label Elements

- 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+P3112.3 Physical/Chemical Hazards: Non-combustible; non-explosive; degrades at >37°C/extreme pH; no hazardous chemical reactions under normal use2.4 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 irritation2.5 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 Glargine (99.8%, CAS:113102-64-0) - 51 amino acid long-acting insulin analogue
- **Excipients:** Glycine (0.2%, non-hazardous lyoprotectant/stabilizer)
- **Hazardous Ingredients:** None (hazards from biological/allergenic effects only)
- **Molecular Weight:** 6063.9 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, CO<sub>2</sub>, 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 12h; reconstituted solution stored at 2-8°C for ≤48h.

- **Incompatibilities:** Extreme pH (pH<6/pH>9), high temperature (>37°C), proteolytic enzymes, strong oxidizers/reducing agents, heavy metal ions
- **Shelf Life:** 36 months (unopened, 2-8°C); 48 hours (reconstituted 1mg/mL PBS solution, 2-8°C)

### SECTION 8: Exposure Controls/Personal Protection

- **Occupational Exposure Limits:** No official OEL for Insulin Glargine; 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 (pH7.0-8.0); slightly soluble in water; insoluble in organic solvents
- pH Value (1mg/mL in PBS, 25°C): 7.0-8.0
- Density: 1.3-1.5 g/cm<sup>3</sup> (lyophilized powder)
- Melting Point: Decomposes (>90°C)
- Boiling Point: N/A (decomposition)
- Flash Point: Non-combustible
- Autoignition Temperature: N/A
- Viscosity: 3-7 mPa·s (1mg/mL PBS solution)
- Isoelectric Point: 5.4 (theoretical)
- Hygroscopy: Slight (absorbs moisture in high humidity)

### SECTION 10: Stability and Reactivity

- **Stability:** Chemically stable at 2-8°C (sealed/protected from light); stable in neutral buffer (pH7.0-8.0); 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 LD<sub>50</sub> (Rat): >10000 mg/kg (no oral bioavailability, no acute toxicity)
- Dermal LD<sub>50</sub> (Rabbit): >10000 mg/kg (mild skin irritation only)
- Inhalation LC<sub>50</sub> (Rat): >5 mg/m<sup>3</sup>/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 LC<sub>50</sub>): >5000 mg/L/96h (non-toxic)
- Aquatic Toxicity (Daphnia EC<sub>50</sub>): >5000 mg/L/48h (non-toxic)
- Persistence: Fully biodegradable (protein hydrolysis by environmental enzymes); no environmental accumulation
- Bioaccumulative Potential: None (log K<sub>oc</sub> <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:** 16 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 48h); sensitive individuals should avoid contact; amino acid sequence conforms to standard insulin glargine.

