



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

Product Name: Porcine Insulin **CAS-No.:** 12584-58-6 **Product Number:** PI-20260215 **Brand:** SIGALD **Revision Date:** 15 FEB 2026

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

1.1 Product Identifiers

- Synonyms: Porcine pancreatic insulin; Insulin porcine; Pancreatic hormone (porcine) 1.2

Supplier Details

- Company: NEWAY SINOPHC TECH. LIMITED
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- 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 diabetes 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 insulin-allergic individuals.

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 2.3

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; insulin allergy cross-reactivity risk; hypoglycemia risk if accidental parenteral exposure. 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.

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SECTION 3: Composition/Information on Ingredients

- **Substance / Mixture:** Pure polypeptide substance
- **Active Component:** Porcine Insulin (CAS:12584-58-6) | 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



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- Inhaled: Move to fresh air; rest in comfortable breathing position; consult a doctor if cough/chest discomfort persists (monitor blood glucose if exposed in large amounts).
 - 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 blood glucose levels for hypoglycemia.
- 4.2 Symptoms:** Nausea/vomiting (ingestion); eye burning/tearing/blurred vision; skin redness/urticaria (allergic reaction); hypoglycemia (dizziness, sweating, confusion) if systemic exposure.
- 4.3 Medical Attention:** Symptomatic treatment; no specific antidote; glucose supplementation for hypoglycemia; antihistamines/corticosteroids for allergic reactions; ophthalmic care for eye irritation.
- 4.4 Notes to Physician:** Inform of product composition (porcine insulin) and exposure route/amount; monitor blood glucose; assess for insulin allergy cross-reactivity.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, CO₂, dry powder (all suitable)

5.2 Special Hazards: Non-combustible; decomposes at >150°C (ambient)/>100°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 ≤40%) ventilated area (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 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 **low-humidity clean room (RH ≤40%)**; use dry sterile 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 insulin-allergic personnel before operation.
 - Avoid parenteral contact (injection); use protective gloves for all handling to prevent skin absorption.
- 7.2 Safe Storage**

- Storage Conditions: **Ultra-low temperature (-20°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.
- Storage Class (TRGS 510): 10 (Toxic Solids, Non-combustible)
- Shelf Life: 36 months (unopened, -20°C vacuum storage); 7 days (4°C refrigerated, after opening)
- Storage Segregation: Store separately from water-containing reagents, proteolytic enzymes, food/feed; store in dedicated polypeptide ultra-low temperature freezer.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national limit; recommended TWA: 0.05 mg/m³ (inhalable dust)

8.2 Exposure Controls

- Engineering Controls: Low-humidity clean room (RH ≤40%); local exhaust ventilation (LEV) for dust-generating operations; anhydrous air supply system.
- Personal Protective Equipment (PPE)
 - Eye/Face: Chemical safety goggles (mandatory)
 - Skin: Powder-free nitrile rubber gloves (≥0.18mm); disposable clean lab coat
 - 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)
- Hygiene: Change contaminated lab coat immediately; wash hands with water after handling; no special hygiene measures (minimal skin absorption).

SECTION 9: Physical and Chemical Properties

- Physical State: Lyophilized powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: Decomposes (≥150°C ambient; ≥100°C vacuum)
- Boiling Point: N/A (decomposes before boiling)
- Flammability: Non-combustible
- Flash Point: N/A
- Autoignition Temperature: >300°C
- Solubility: Soluble in water (pH 2.5-3.5, acidic condition), dilute HCl/NaOH; slightly soluble in ethanol; insoluble in non-polar organic solvents (hexane/ether)
- Density (25°C): 1.26 g/cm³
- Particle Size: 200-300 mesh (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None



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- pH Value: 5.0-7.0 (1mg/mL aqueous suspension, 25°C)
- Viscosity: N/A (solid); 3-7 mPa·s (10mg/mL acidic aqueous solution)
- Hygroscopy: High (absorbs moisture at RH >40%)
- Vapor Pressure (25°C): < 0.1 hPa

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable at -20°C vacuum/dry storage; stable at 4°C for 7 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/heavy metal ions.**10.3 Conditions to Avoid:** Moisture (RH >40%), high temperature (>25°C), repeated freeze-thaw, strong acids/bases, proteolytic enzymes, heavy metal ions.**10.4 Incompatible Materials:** Excess water, concentrated HCl/H₂SO₄, NaOH/KOH, trypsin/pepsin, papain, copper/zinc ions, hydrogen peroxide.**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, LD₅₀) = 2900 mg/kg; Dermal (Rabbit, LD₅₀) >5000 mg/kg; Inhalation (Rat, LC₅₀) >1 mg/m³ (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 Sensitization: Positive (human/animal tests); insulin allergy cross-reactivity with human/bovine insulin.
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP.
- Reproductive Toxicity: No adverse reproductive effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation.
- Target Organ Toxicity: Eyes, skin, endocrine system (hypoglycemia via systemic exposure); no chronic target organ toxicity.

SECTION 12: Ecological Information

12.1 Toxicity: Fish (Zebrafish, LC₅₀) >1000 mg/L (96h); Daphnia (EC₅₀) >1000 mg/L (48h); Algae (EC₅₀) >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 = 1-3 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 acidic 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.



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SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** High-value waste: reprocess via lyophilization for reuse; Low-value waste: incinerate at >800°C via licensed hazardous waste facilities (non-toxic ash); Aqueous waste: dilute 1:100 and discharge to biological wastewater treatment system (biodegradable).13.2

Packaging Waste: Rinse with anhydrous ethanol; dry thoroughly; dispose as non-hazardous plastic/glass waste; recycle dedicated polypeptide 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. (Porcine Insulin)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: Mandatory cold chain transport (-20°C±5°C);** vacuum-sealed packaging with anhydrous desiccant; styrofoam cooler with dry ice; mark "**Do Not Thaw/Refreeze**"; avoid temperature fluctuation, collision, moisture.14.7 **Incompatible Materials:** Avoid transport with water-containing products, proteolytic enzymes, strong acids/bases, heavy metal salts, 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)
- International: GHS (Rev.9) Cat.4 Acute oral toxicity; REACH (EU) Registered; TSCA (US) Listed; USP/EP/FDA compliant; FDA-approved for diabetes treatment.15.2 **Other:** Comply with local pharmaceutical import/export, cold chain transport and hazardous chemical regulations; mark for insulin 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-cold chain storage/transport or non-compliance with safety precautions.
- Pharmaceutical grade Porcine Insulin meets global pharmacopoeia standards; for formulated injectable pharmaceutical products only (GMP conditions).
- For further technical/safety information, contact the supplier's polypeptide R&D/EHS department (cold chain guidance provided).