



# 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:** Recombinant Human Interferon  $\alpha$ -2b (rIFN  $\alpha$ -2b)**CAS-No.:** 98530-12-2**Product**

**Number:** IFN-20260228**Brand:** SIGALD**Revision Date:** 28 FEB 2026

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

#### 1.1 Product Identifiers

- Synonyms: Interferon  $\alpha$ -2b (recombinant); rIFN  $\alpha$ -2b; Human Interferon alpha-2b

#### 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 (antiviral/antitumor/immunomodulator); biomedical research reagent; virology/cell biology research; cell culture supplement.
- Uses Advised Against: Not for direct injection (unformulated); no unapproved food/cosmetic/industrial use; avoid use in interferon-allergic individuals and autoimmune disease patients.

### SECTION 2: Hazards Identification

2.1 **GHS Classification:** Eye irritation, Category 2 (H319); Skin sensitization, Category 1 (H317); Specific target organ toxicity (single exposure), Category 3 (General body effects) (H373)2.2

#### GHS Label Elements

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- Hazard Statements: H317 - May cause an allergic skin reaction; H319 - Causes serious eye irritation; H373 - May cause damage to organs through prolonged or repeated exposure
- Precautionary Statements: P261, P280, P305+P351+P338, P333+P313, P3142.3 **Physical and**

**Chemical Hazards:** No physical/chemical hazards; non-combustible; highly hygroscopic2.4

**Health Hazards:** May cause allergic skin/respiratory reactions in sensitive individuals; causes serious eye irritation; may cause systemic organ damage via prolonged/repeated systemic exposure; flu-like symptoms (fever/fatigue) with 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 rapidly on moisture absorption); no additional hazards identified.

### SECTION 3: Composition/Information on Ingredients

- **Substance / Mixture:** Pure recombinant glycoprotein



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- **Active Component:** Recombinant Human Interferon a-2b (CAS:98530-12-2) | Concentration:  $\geq 99.0\%$  | Classification: Eye irritation Cat.2; Skin sensitization Cat.1; Target organ toxicity Cat.3

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move to fresh air; administer oxygen if breathing is difficult; consult a doctor immediately (monitor for allergic/flu-like symptoms).
  - Skin Contact: Rinse skin with running water and mild soap for 15 mins; remove contaminated clothing; consult a doctor if redness/itching/swelling persists (assess for allergic reaction).
  - Eye Contact: Rinse eyes thoroughly with sterile water for 20-30 mins (hold eyelids open); remove contact lenses; **immediately consult an ophthalmologist.**
  - Swallowed: Rinse mouth with water; do not induce vomiting; consult a doctor immediately (monitor for gastrointestinal/systemic symptoms).
- 4.2 Symptoms:** Eye burning/tearing/blurred vision; skin redness/urticaria/asthma (allergic reaction); fever/fatigue/muscle pain (flu-like symptoms); headache/nausea (systemic exposure); organ damage (prolonged exposure).
- 4.3 Medical Attention:** Symptomatic treatment; antihistamines/corticosteroids for allergic reactions; ophthalmic care for eye irritation; antipyretics for flu-like symptoms; supportive care for organ damage; no specific antidote.
- 4.4 Notes to Physician:** Inform of product composition (recombinant human interferon a-2b) and exposure route/amount; monitor for flu-like/allergic symptoms; assess organ function for prolonged exposure.

## 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  $>200^{\circ}\text{C}$  into non-toxic amino acids/carbohydrates; no toxic combustion/decomposition fumes generated.
- 5.3 Firefighter Advice:** Wear standard fire-fighting gear (SCBA recommended for large fires); cool containers with water spray to prevent moisture absorption/protein degradation; no toxic fume inhalation risk.

## SECTION 6: Accidental Release Measures

- 6.1 Personal Precautions:** Wear N95 dust mask, chemical safety goggles + face shield, double-layer nitrile gloves, impermeable lab coat; operate in low-humidity (RH  $\leq 30\%$ ) well-ventilated area.
- 6.2 Environmental Precautions:** No special measures needed; spilled powder 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 vacuum moisture-proof container for reprocessing/disposal.
  - Large Spill: Contain with anhydrous inert material (anhydrous silica gel); collect into sealed vacuum container; do not rinse with water (high hygroscopy); dispose of collected material as hazardous waste.
- 6.4 Reference:** See Section 13 for disposal details.

## SECTION 7: Handling and Storage

### 7.1 Safe Handling



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- Operate in a **Grade A/B low-humidity clean room (RH ≤30%)**; use sterile disposable equipment; avoid dust generation/inhalation and skin/eye contact.
  - Do not eat/drink/smoke in the work area; wash hands thoroughly with sterile water after handling; identify interferon/allergic personnel before operation; limit prolonged/repeated contact.
- ### 7.2 Safe Storage
- Storage Conditions: **-20°C±5°C (ultra-low temperature)**, dry, dark, **vacuum-sealed**; secondary packaging with anhydrous desiccant; avoid repeated freeze-thaw cycles.
  - Incompatibilities: Water/moisture, strong acids/bases, proteolytic enzymes, heavy metal ions, oxidizing agents, organic solvents.
  - Storage Class (TRGS 510): 10 (Toxic Solids, Non-combustible)
  - Shelf Life: 36 months (unopened, -20°C vacuum storage); 7 days (2-8°C refrigerated, after opening)
  - Storage Segregation: Store separately from food/feed, pharmaceuticals, strong acids/bases, proteolytic enzymes; store in dedicated recombinant protein ultra-low temperature freezer (locked).

## 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) with full facepiece 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; regular medical monitoring for prolonged exposure personnel.

## SECTION 9: Physical and Chemical Properties

- Physical State: Lyophilized powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: Decomposes (>200°C)
- Boiling Point: N/A (decomposes before boiling)

- Flammability: Non-combustible
- Flash Point: N/A
- Autoignition Temperature: >350°C
- Solubility: Soluble in water, dilute phosphate buffer (pH 6.5-7.5); insoluble in organic solvents (ethanol/ether/hexane/chloroform)
- Density (25°C): 1.30 g/cm<sup>3</sup>
- Particle Size: 200-300 mesh (pharmaceutical grade)
- Explosive Properties: Non-explosive
- Oxidizing Properties: None
- pH Value: 6.5-7.5 (1mg/mL aqueous solution, 25°C)
- Hygroscopy: **High** (absorbs moisture at RH >30%)
- Vapor Pressure (25°C): < 0.01 hPa
- Viscosity: N/A (solid); 4-8 mPa·s (10mg/mL aqueous solution, 25°C)

## SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable at -20°C vacuum/dry storage; stable for 7 days at 2-8°C (after opening); degrades rapidly at room temperature/moisture/high temperature.

10.2 **Hazardous Reactions:** No hazardous reactions; hydrolyzes in strong acids/bases to amino acids/carbohydrates; degrades via enzymatic breakdown/oxidation; denatures at high temperature.

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

10.4 **Incompatible Materials:** 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, glycans; no hazardous decomposition products.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) >5000 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); Parenteral (Mouse, LD<sub>50</sub>) = 800 mg/kg
- Skin Irritation/Corrosion: No irritation (Rabbit, 24h exposure); may cause severe allergic sensitization in susceptible individuals.
- Eye Irritation/Damage: Severe irritation (Rabbit, 24h exposure); reversible with prompt treatment.
- Skin/Respiratory Sensitization: Positive (human/animal tests); high interferon allergy cross-reactivity risk.
- Mutagenicity: No mutagenic effects (Ames test, chromosome aberration test, in vivo micronucleus test).
- Carcinogenicity: Not classified as carcinogenic by IARC/EPA/NTP; antitumor activity in clinical use.



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- Reproductive Toxicity: No adverse reproductive/teratogenic effects at therapeutic dosages; avoid high-dose exposure during pregnancy/lactation (systemic risk).
- Target Organ Toxicity: Liver/Kidney (prolonged/repeated systemic exposure); immune system (dysregulation); eyes/skin (direct contact); general body (flu-like symptoms).
- Chronic Toxicity: Mild liver/kidney dysfunction with prolonged systemic exposure; reversible with dose cessation.

### 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 = 0.5-1 day (ambient temperature). 12.3 **Bioaccumulative Potential:** None (hydrolyzes to amino acids/glycans; 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 products act as soil nutrients; promotes microbial growth.

### SECTION 13: Disposal Considerations

13.1 **Waste Treatment:** All waste (powder/solution) is **hazardous waste**; incinerate at >900°C via licensed hazardous waste facilities with gas treatment; no discharge to water/soil/sewage system; do not dispose of with ordinary waste. 13.2 **Packaging Waste:** Decontaminate with anhydrous ethanol; dry thoroughly; dispose as biohazardous plastic/glass waste via licensed facilities; no recycling with non-pharmaceutical packaging.

### SECTION 14: Transport Information

14.1 **UN Number:** ADR/RID/IMDG/IATA: 2811 14.2 **UN Proper Shipping Name:** Toxic solids, organic, n.o.s. (Recombinant Human Interferon  $\alpha$ -2b) 14.3 **Transport Hazard Class:** 6.1 (Toxic substances) 14.4 **Packaging Group:** III 14.5 **Environmental Hazards:** IMDG: Marine pollutant (No) 14.6 **Special Precautions:** **Ultra-low temperature cold chain transport (-20°C±5°C)**; vacuum-sealed packaging with anhydrous desiccant; cryogenic dry ice cooler with temperature monitor; shock-proof/moisture-proof outer packaging; mark "**Keep Frozen**", "**Do Not Thaw/Refreeze**", "**Toxic**"; licensed hazardous chemical cold chain transport only; 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, pharmaceuticals.

### 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; Medical Device Regulation.



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- International: GHS (Rev.9) Cat.2 Eye irritation; REACH (EU) Registered; TSCA (US) Listed; USP/EP/FDA compliant; FDA-approved for antiviral/antitumor clinical use.15.2 **Other:** Comply with local pharmaceutical import/export (recombinant biological product), ultra-low temperature cold chain transport and hazardous chemical regulations; mark for interferon allergy and organ toxicity risk; comply with GMP for pharmaceutical use.

### **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.
- Pharmaceutical grade Recombinant Human Interferon a-2b meets global pharmacopoeia and recombinant biological product standards; for formulated pharmaceutical/biological 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).



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