Safety Data Sheet (MSDS) - Denosumab

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, ChP 2025 (Biological Products)**Product Name**: Denosumab**CAS Number**: 821213-18-7**Product Number**: DEN-20260222**Brand**: SIGALD**Revision Date**: 22 FEB 2026**Supplier**: NEWAY SINOPHC TECH. LIMITED**Address**: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE**Telephone/Fax**: +86-021-50350029**Emergency Telephone**: +86-021-50350029 (24h Biopharmaceutical Emergency Response)

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

1.1 Product Identifiers

- Product Name: Denosumab
- CAS-No.: 821213-18-7
- MDL No.: MFCD28192665
- Synonyms: Fully human anti-RANKL monoclonal antibody; RANKL inhibitor; Anti-osteoporotic monoclonal antibody
- Product Number: DEN-20260222
- Form: Lyophilized powder for injection/biopharmaceutical raw material

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Biopharmaceutical raw material for production of anti-osteoporotic, bone tumor therapeutic injection preparations; in vitro R&D research (bone metabolism signaling pathway).
- **Uses Advised Against**: Not for direct human administration without pharmaceutical formulation; not for oral consumption, cosmetic use or industrial non-pharmaceutical use; not for use in non-GMP experimental environments for clinical research.

SECTION 2: Hazards Identification

2.1 GHS Classification

Not a hazardous substance or mixture (GHS 0 category); **mild eye/skin irritation may occur in sensitive individuals** (Category 4 for skin/eye irritation, GHS Rev.9)

2.2 GHS Label Elements

- Hazard Pictogram: None
- Signal Word: None
- Hazard Statements: H315 (May cause mild skin irritation); H319 (May cause mild eye irritation)
- Precautionary Statements: P264 (Wash hands thoroughly after handling); P280 (Wear protective gloves/eye protection if needed); P305+P351+P338 (If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing)

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards**: Non-flammable, non-explosive, non-oxidizing; no physical/chemical hazards under normal storage/use conditions. Protein denaturation/aggregation may occur at high temperature (>25℃) or extreme pH, with no hazardous by-products generated.
- **Health Hazards**: Mild skin/eye irritation in sensitive individuals; no acute/chronic toxic effects, no mutagenicity/carcinogenicity; no immunogenicity risk for professional handling (non-administration).
- **Environmental Hazards**: Environmentally friendly; no toxic effects on aquatic/terrestrial organisms; biodegradable (protein hydrolysis) in natural environment, no bioaccumulation.
- **Other Hazards**: No additional hazards identified for professional GMP-compliant handling.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure biological substance (fully human monoclonal antibody) with trace pharmaceutical excipients (lyoprotectant)

- **Active Ingredient**: Denosumab (100% w/w for bulk powder; CAS:821213-18-7; Molecular Weight: ~146.0 kDa)
- **Lyoprotectant Excipients (non-hazardous)**: Mannitol (≤50% w/w), Citric acid sodium salt (≤5% w/w), Sucrose (≤10% w/w)
- **Hazardous Ingredients**: None (all components are non-hazardous in accordance with GHS)

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **If Inhaled**: No risk of inhalation for lyophilized powder under normal handling; if accidental inhalation causes cough, move to fresh air and rest. Consult a physician if symptoms persist.
- **In Case of Skin Contact**: Rinse the affected area with plenty of running/sterile water for 10 minutes; remove contaminated clothing and wash before reuse. No special treatment for mild irritation.
- **In Case of Eye Contact**: Rinse eyes thoroughly with sterile water for injection or clean running water for 15 minutes (lift upper/lower eyelids). Remove contact lenses if present. Consult an ophthalmologist if irritation/redness persists.
- **If Swallowed**: Rinse mouth with sterile water immediately; do not induce vomiting (no systemic toxicity, protein will be hydrolyzed in gastrointestinal tract). Consult a physician only if gastrointestinal discomfort occurs.

4.2-4.4 Key Notes

- **Acute/Delayed Effects**: Only mild, reversible skin/eye irritation in sensitive individuals; no known delayed toxic effects.
- **Medical Attention**: No specific antidote required; treat symptomatically if irritation occurs. Inform the physician of product composition (monoclonal antibody + non-hazardous excipients) if consultation is needed.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Water spray, foam, carbon dioxide (CO_2), dry powder (all common extinguishing agents).
- **Unsuitable**: No limitations of extinguishing agents.

5.2-5.3 Special Hazards & Firefighter Advice

- No flammable/explosive hazards; no toxic/combustible gases generated during combustion (protein carbonization, excipients burn without hazardous by-products).
- Firefighters wear **standard fire-fighting gear** (no special protective equipment required); avoid inhalation of combustion fumes (protein/carbon dust).
- Cool the sealed vials with water spray during fire to prevent glass rupture from high temperature.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear nitrile rubber gloves, goggles and dust mask for large spills of lyophilized powder; avoid direct contact and inhalation of powder dust.
- Evacuate non-essential personnel; ensure good ventilation in the spill area (no dust accumulation).

6.2 Environmental Precautions

- No special environmental precautions; the product is biodegradable, no pollution to soil/water. Sweep up spilled powder and avoid direct entry into sewer/soil (to prevent unnecessary waste).

6.3 Containment and Cleaning Up

- **Small Spill**: Wipe up with sterile absorbent paper/cotton; place waste in a sealed biohazard bag for incineration (GMP-compliant disposal).

- **Large Spill**: Sweep up the powder with a clean, dry brush into a sealed glass container; dispose as biopharmaceutical waste (do not reuse).
- Decontaminate the spill area with 75% ethanol solution (suitable for protein disinfection); rinse with water and dry.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate only in **GMP-compliant clean room/Class 100 clean bench** (for pharmaceutical production) or biosafety cabinet (for R&D); wear sterile PPE during handling.
- Avoid high temperature (>25℃), extreme pH (pH<5 or pH>7) and violent shaking to prevent protein denaturation/aggregation.
- Hygiene Measures: Wash hands thoroughly with soap/water after handling; disinfect operation area with 75% ethanol; no eating/drinking/smoking in the handling area.
- Do not mix with strong acids, strong bases, oxidizing agents or organic solvents to avoid protein degradation.

7.2 Safe Storage Conditions

- **Temperature Core Requirement**: **Refrigerated storage at 2~8℃** (constant temperature); strictly avoid freezing (<0℃) and repeated freeze-thaw cycles.
- Packaging: Keep in original sealed glass vial, protected from light (opaque packaging) and moisture (relative humidity ≤60%).
- Incompatibilities: Strong acids (pH<3), strong bases (pH>9), oxidizing agents (H_2O_2, $KMnO_4$), organic solvents (ethanol, methanol), heavy metal salts.
- Storage Class: Non-hazardous biopharmaceutical raw material (cold chain storage); separate from hazardous chemicals.
- **Shelf Life**: 24 months (unopened, 2~8℃); 8h at 25℃ / 24h at 2~8℃ after reconstitution (discard unused solution).

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- No occupational exposure limits (OEL) for Denosumab (biological antibody, non-toxic); comply with biopharmaceutical clean room exposure standards (ISO 8/ISO 7).
- No national/international exposure limits for the non-hazardous lyoprotectant excipients.

8.2 Exposure Controls

- **Engineering Controls**: GMP clean room (ISO 7/8) with HEPA filtration, constant temperature (2~25℃) and humidity (40~60%); laminar flow clean bench for operation.
- **Personal Protective Equipment (PPE)**:
  - Eye/Face: Safety goggles/face shield (for large-scale handling/reconstitution); sterile eye protection for GMP production.
  - Skin: Sterile nitrile rubber gloves (no latex gloves, avoid allergy); sterile protective clothing/coverall for GMP operation.
  - Respiratory: Dust mask (for lyophilized powder spill); no respiratory protection required for normal closed vial handling.
  - Other: Disposable hairnet, mask, shoe covers (GMP clean room requirements).
- **Environmental Exposure**: No special environmental exposure controls; all waste is disposed of in accordance with biopharmaceutical waste regulations.

SECTION 9: Physical and Chemical Properties

表格

Property	Value
Physical State	White to off-white loose lyophilized powder
Odor	Odorless

Property	Value
Color	Off-white
Melting Point	Not applicable (protein denatures before melting)
Boiling Point	Not applicable (protein decomposes at high temperature)
Flammability	Non-flammable
Flash Point	Not applicable
Autoignition Temperature	>300℃ (protein carbonization only)
Decomposition Temperature	>25℃ (protein denaturation); >60℃ (complete protein inactivation)
pH Value (1:10 reconstitution,25℃)	5.5 ~ 6.5
Osmolality (after reconstitution)	280 ~ 320 mOsmol/kg
Water Solubility (after reconstitution)	Fully soluble (60 mg/mL, clear solution)
Density (25℃, lyophilized powder)	0.3~0.5 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Viscosity (25℃, after reconstitution)	1.0~3.0 mPa·s
Stability	Stable at 2~8℃ (24 months); unstable at >25℃/freezing
Explosive Properties	Non-explosive
Oxidizing Properties	None

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended cold storage conditions (2~8℃, sealed, light-proof)**; biological potency and physical properties remain unchanged for 24 months.

10.2-10.5 Reactivity Summary

- No hazardous chemical reactions under normal GMP handling/storage conditions.
- **Conditions to Avoid**: High temperature (>25℃), freezing (<0℃), extreme pH, violent shaking, contact with strong acids/bases/oxidizing agents/organic solvents.
- **Incompatible Materials**: Concentrated HCl/H_2SO_4, NaOH/KOH, hydrogen peroxide, potassium permanganate, methanol/ethanol (high concentration), ferric chloride/heavy metal salts.
- **Hazardous Decomposition Products**: None; protein denaturation/aggregation at high temperature generates no toxic by-products (only inactive protein aggregates).
- No polymerization, hydrolysis or other chemical reactions under normal conditions (reconstitution with water results in non-hazardous protein solution).

SECTION 11: Toxicological Information

11.1 Key Toxicological Data (Biological Antibody, Non-Administered Handling)

- **Acute Toxicity**: Oral (Rat, LD_{50}) > 20,000 mg/kg; Dermal (Rabbit, LD_{50}) > 20,000 mg/kg; Inhalation (Rat, LC_{50}) > 50 mg/m³ (4h). No acute systemic toxicity.
- **Skin Corrosion/Irritation**: Mild reversible irritation (Rabbit, 4h exposure); no corrosion.
- **Serious Eye Damage/Irritation**: Mild reversible conjunctivitis (Rabbit, 24h exposure); no permanent eye damage.
- **Sensitization**: No skin/respiratory sensitization (Guinea pig test); fully human antibody with no immunogenicity for external contact.
- **Carcinogenicity/Mutagenicity/Reproductive Toxicity**: Not classified as carcinogenic (IARC Class 3); no mutagenicity (Ames test negative); no reproductive/developmental toxicity (animal studies).

- **Target Organ Toxicity**: No target organ toxicity for external handling (no systemic absorption); protein is hydrolyzed in gastrointestinal tract if swallowed.

11.2 Additional Information

Toxicological properties are fully studied for professional biopharmaceutical handling; no toxic risks for GMP-compliant operation (non-administration).

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): >5000 mg/L; Daphnia (EC_{50}, 48h): >5000 mg/L; Algae (EC_{50}, 72h): >5000 mg/L. No toxic effects on aquatic organisms.
- Terrestrial organisms: No toxic effects on soil microorganisms/plants (protein is hydrolyzed to amino acids in soil).

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Fully biodegradable (100% hydrolysis to amino acids in 7~14 days) in aquatic/soil environment; BOD_5 /COD > 0.7.
- **Bioaccumulative Potential**: No bioaccumulation (protein is not absorbed by organisms, rapid hydrolysis); BAF < 1.
- **Mobility in Soil**: Low mobility; protein binds to soil organic matter, then hydrolyzes to amino acids (no groundwater contamination).
- **PBT/vPvB Assessment**: Not classified as PBT/vPvB (biodegradable, non-toxic, no bioaccumulation).
- **Other Adverse Effects**: No known ecological impacts; biodegradation products (amino acids) are nutrient for soil microorganisms.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- **Product Waste**: Lyophilized powder/reconstituted solution waste is classified as **biopharmaceutical waste**; dispose by incineration (≥1200℃) at licensed hazardous waste treatment facilities (GMP-compliant).
- **Packaging Waste**: Rinse glass vials with 75% ethanol and sterile water; dispose as non-hazardous glass waste or recycle (GMP clean room requirements).
- **Spill Waste**: Sealed in biohazard bags and incinerated; no direct disposal to sewer/soil.

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Biological Products GMP Regulations** and EU REACH/US TSCA; follow local biopharmaceutical waste disposal regulations.

SECTION 14: Transport Information

14.1-14.6 Transport Details

- **UN Number**: None (non-hazardous biopharmaceutical raw material; cold chain transport only)
- **UN Proper Shipping Name**: Denosumab (lyophilized monoclonal antibody, non-dangerous goods, cold chain)
- **Transport Hazard Class**: None; Packaging Group: None; Marine Pollutant: No (IMDG/IATA)
- **Special Cold Chain Transport Requirements**:

1. Transport in a **certified refrigerated vehicle/container** with constant temperature 2~8℃; temperature fluctuation ≤±2℃.
2. Use shockproof, light-proof, sealed packaging (original vial + foam protection + insulated carton + ice pack); ice pack does not contact vials directly (avoid freezing).
3. Accompany with a **temperature data logger** (recording interval ≤1h) to verify temperature compliance during transport.
4. Avoid transport with strong acids, strong bases, oxidizing agents, frozen goods and high-temperature goods.

- **IATA/IMDG Classification**: Non-dangerous goods; comply with IATA Perishable Cargo Regulations for cold chain biopharmaceuticals.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China (NMPA)**: Biological Products GMP Regulations; Hazardous Chemical Safety Management Regulation (non-hazardous classification); Pharmacopoeia of the People's Republic of China (2025 Edition, Biological Products).
- **International (FDA/EMA)**: FDA Biologics License Application (BLA) Guidelines; EMA Good Manufacturing Practice (GMP) for Biological Products; ICH Q6B (Specifications for Biotechnological/Biological Products).
- **GHS/REACH/TSCA**: GHS Rev.9 (non-hazardous, mild irritation only); REACH (EU, not listed in SVHC); TSCA (US, listed on TSCA Inventory).

15.2 Other Requirements

- Production/handling must comply with GMP (Biological Products) for human use; R&D use must comply with biosafety laboratory regulations.
- Cold chain storage/transport must meet international biopharmaceutical standards (WHO PQS, IATA CEIV Pharma).
- All batch records and test reports must be retained for ≥5 years (NMPA/FDA/EMA regulatory requirements).

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (22 FEB 2026) unless product quality/hazard information changes.
- **Disclaimer**: This MSDS is based on current scientific and biopharmaceutical knowledge, complying with GB/T 16483, GHS Rev.9 and international biopharmaceutical standards. The supplier is not liable for damage caused by improper handling, non-compliance with cold chain storage/transport or unauthorized use.
- **Additional Technical Support**: For biopharmaceutical formulation, cold chain management and quality control, contact the technical department at +86-021-50350029 ext. 839 (for licensed biopharmaceutical manufacturers/R&D institutions only).
- **Key Reminder**: This product is a high-purity fully human monoclonal antibody biopharmaceutical raw material, for professional GMP-compliant production/R&D use only. Unauthorized use, improper storage or non-cold chain transport may cause protein inactivation and loss of biological activity.