Safety Data Sheet (MSDS)

(According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

Product Name: Budesonide**Product Number**: BUD-20260215**Brand**: SIGALD**CAS Number**: 51333-22-3**Revision Date**: 15 FEB 2026

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

1.1 Product Identifiers

- Product Name: Budesonide
- Synonyms: (RS)-11β,16a,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde
- CAS-No.: 51333-22-3
- Molecular Formula: $C_{25}H_{34}O_6$
- Molecular Weight: 430.54 g/mol

1.2 Details of the supplier of the safety data sheet

- 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

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

1.4 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical raw material for respiratory system and anti-inflammatory drugs, research reagent for glucocorticoid mechanism study, fine chemical intermediate.
- Uses Advised Against: Not for unauthorized clinical use; not for cosmetic use; not for animal feed additive; not for release to the natural environment.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity (oral, rat): Category 4 (LD_{50} = 2300 mg/kg)
- Reproductive toxicity: Category 1B
- Target organ toxicity (repeated exposure): Category 2 (endocrine system, liver, adrenal gland)
- Hazard to the aquatic environment (long-term): Category 3

2.2 GHS Label Elements

- Hazard Pictograms: GHS07 (Exclamation mark), GHS08 (Health hazard), GHS09 (Environment)
- Signal Word: Danger
- Hazard Statements:
  - H302: Harmful if swallowed
  - H360: May damage fertility or the unborn child
  - H373: May cause damage to organs (endocrine system, liver, adrenal gland) through prolonged or repeated exposure

- H412: Harmful to aquatic life with long lasting effects
- Precautionary Statements:
- P201: Obtain special instructions before use
- P202: Do not handle until all safety precautions have been read and understood
- P264: Wash skin thoroughly after handling
- P270: Do not eat, drink or smoke when using this product
- P273: Avoid release to the environment
- P280: Wear protective gloves/eye protection/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
- P308+P313: If exposed or concerned: Get medical advice/attention
- P391: Collect spillage
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

2.3 **Physical and Chemical Hazards**: No physical or chemical hazards under normal use; combustible at high temperature (>300℃); decomposes when heated to melting point.2.4 **Health Hazards**: Harmful if swallowed; reproductive toxicant; prolonged exposure may cause endocrine disorder, adrenal gland suppression, liver function damage and immune system inhibition; no skin/eye irritation in normal handling.2.5 **Environmental Hazards**: Harmful to aquatic life with long-lasting effects; low biodegradability, high bioaccumulation potential in aquatic organisms and easy to disrupt aquatic endocrine system.2.6 **Other Hazards**: No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure Substance
- Active Ingredient: Budesonide (100%, CAS:51333-22-3)
- No hazardous impurities present above the specified limit values.

SECTION 4: First Aid Measures

4.1 **Description of First-Aid Measures**

- If Inhaled: Move the victim to fresh air immediately, keep the respiratory tract unobstructed. If breathing is difficult, give oxygen and call a POISON CENTER/doctor at once.
- In Case of Skin Contact: Rinse the skin with plenty of soap and running water for at least 5 minutes. Remove contaminated clothing and wash it before reuse. No special treatment is needed if no irritation occurs.
- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes, lifting the upper and lower eyelids occasionally. Remove contact lenses if worn. Consult a doctor if irritation or discomfort persists.
- If Swallowed: Do not induce vomiting. Rinse the mouth with water immediately. Call a POISON CENTER/doctor and provide the product information for medical treatment.

4.2 **Most Important Symptoms and Effects**

- Acute Effects: Nausea, vomiting, abdominal pain, dizziness after accidental ingestion; no obvious acute toxicity for skin and inhalation contact in short term.
- Delayed Effects: Prolonged or repeated exposure may cause hormonal imbalance, adrenal cortex suppression, liver function abnormalities, immune system inhibition and reproductive system damage.

4.3 **Indication of Immediate Medical Attention**

- Immediate medical attention is required for accidental ingestion, prolonged exposure, suspected organ damage or reproductive system impact. Provide a copy of this MSDS to the attending physician.

SECTION 5: Firefighting Measures

5.1 **Extinguishing Media**

- Suitable Extinguishing Media: Water spray, dry powder, foam, carbon dioxide (CO_2).
- Unsuitable Extinguishing Media: No limitations on extinguishing agents.

5.2 **Special Hazards Arising from the Substance or Mixture**

- The product is combustible at high temperature; burning may produce toxic fumes including carbon monoxide, carbon dioxide and small molecular hydrocarbon compounds.
- Decomposes at melting point with no toxic gas release; no explosion risk under normal use and storage conditions.

5.3 **Advice for Firefighters**

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear when fighting fires.
- Fight the fire from a safe distance; prevent the fire runoff from entering sewers, rivers and other water bodies to avoid environmental contamination.

SECTION 6: Accidental Release Measures

6.1 **Personal Precautions, Protective Equipment and Emergency Procedures**

- Wear nitrile rubber gloves, safety glasses, N95 dust mask and protective clothing when handling the spillage.
- Avoid dust formation and inhalation; ensure good ventilation in the spill area.
- Evacuate non-essential personnel from the spill site to a safe area.

6.2 **Environmental Precautions**

- Strictly prevent the spillage from entering soil, sewers, rivers, lakes and other natural water bodies.
- Do not discharge the spilled material directly into the environment.

6.3 **Methods and Materials for Containment and Cleaning Up**

- Small Spill: Sweep up the spilled powder with a dry and clean brush/spatula, collect it in a sealed hazardous waste container for proper disposal.

- Large Spill: Contain the spillage with dry sand to prevent spread, transfer the collected powder to a sealed container by vacuum with HEPA filter for disposal; clean the spill area with ethanol and wipe dry.

6.4 **Reference to Other Sections**: For the disposal of spilled waste, see Section 13.

SECTION 7: Handling and Storage

7.1 **Precautions for Safe Handling**

- Handle the product in a well-ventilated area with dust extraction equipment to avoid dust formation and inhalation.
- Wear the specified personal protective equipment (PPE) during all handling operations (see Section 8).
- Do not eat, drink, smoke or apply cosmetics when handling the product; wash hands and face thoroughly with soap and water after handling.
- Avoid mixing the product with strong oxidizing agents, strong acids, strong bases and organic halides.

7.2 **Conditions for Safe Storage, Including Any Incompatibilities**

- Storage Conditions: Store in a cool refrigerator at 2-8℃, brown glass bottle with aluminum foil seal, protected from light and moisture.
- Storage Class: Dedicated pharmaceutical raw material storage area for glucocorticoid drugs.
- Incompatibilities: Strong oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), strong mineral acids, strong alkalis, halogenated compounds, high temperature (>30℃).
- Shelf Life: 36 months (unopened, under the specified 2-8℃ storage conditions); 6 months after opening (stored at 2-8℃, sealed).
- Store locked up and separate from food, beverages, aquatic products, medical supplies and non-hazardous materials.

SECTION 8: Exposure Controls/Personal Protection

8.1 **Control Parameters**

- No official occupational exposure limits (OEL) for Budesonide; set the internal workplace limit of 0.1 mg/m³ for airborne dust.

8.2 **Exposure Controls**

- Engineering Controls: Install local exhaust ventilation (LEV) and dust extraction equipment in the handling area; conduct regular air quality monitoring in the workplace.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical splash goggles for routine handling; face shield for large-scale powder handling.
  - Skin Protection: Nitrile rubber gloves (thickness ≥0.3 mm), impermeable protective clothing and lab coat.
  - Respiratory Protection: N95 dust mask for routine handling; powered air-purifying respirator (PAPR) for large spills or heavy dust.

- Hand Protection: Replace gloves immediately if they are torn, punctured or contaminated; wash hands after glove removal.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: 220-228℃ (decomposes)
- Boiling Point: Not applicable (decomposes before boiling)
- Flammability: Combustible at high temperature (>300℃)
- Flash Point: >200℃ (Closed Cup)
- Autoignition Temperature: >350℃
- Solubility: Slightly soluble in water; soluble in chloroform, ethanol, DMSO, acetone, dichloromethane; slightly soluble in vegetable oils
- Density (20℃): 1.19 g/cm³ (powder)
- Optical Rotation: +124° to +131° (c=0.5, chloroform, 25℃)
- Vapor Pressure (25℃): <0.0001 hPa (negligible)
- Particle Size: 90% passing 200 mesh
- pH Value: 5.0-7.0 (0.05% suspension in water)
- Hygroscopy: Slightly hygroscopic
- Decomposition Temperature: 220℃ (melting and decomposition)

SECTION 10: Stability and Reactivity

10.1 **Chemical Stability**: Stable under the recommended 2-8℃ and dark storage conditions; decomposes at high temperature (>220℃) and degrades when exposed to light and moisture for a long time.10.2 **Possibility of Hazardous Reactions**: No hazardous reactions occur under normal use and handling conditions.10.3 **Conditions to Avoid**: High temperature, direct sunlight, moisture, contact with strong oxidizing agents, strong acids and strong bases.10.4 **Incompatible Materials**: Strong oxidizing agents, concentrated sulfuric acid, concentrated sodium hydroxide, chlorine-containing compounds, bromine-containing compounds.10.5 **Hazardous Decomposition Products**: Carbon monoxide, carbon dioxide and small molecular hydrocarbons when burned; no toxic decomposition products under normal storage conditions.

SECTION 11: Toxicological Information

11.1 **Information on Toxicological Effects**

- Acute Toxicity: Oral (rat) LD_{50} = 2300 mg/kg (harmful); Dermal (rabbit) LD_{50} >5000 mg/kg (no acute dermal toxicity); Inhalation (rat) LC_{50} >10 mg/m³ (4-hour exposure).
- Skin Corrosion/Irritation: No skin irritation (rabbit, 4-hour exposure test).
- Serious Eye Damage/Eye Irritation: No eye irritation (rabbit, 24-hour exposure test).

- Reproductive Toxicity: Category 1B; animal tests show it may cause fetal development abnormalities, reduced fertility and reproductive system damage.
- Target Organ Toxicity (Repeated Exposure): May cause endocrine system disorder, adrenal cortex suppression, liver function abnormalities and immune system inhibition after prolonged exposure.
- Carcinogenicity: Not classified as a carcinogen by IARC, EPA or NTP.
- Mutagenicity: No mutagenic effects observed in standard in vitro and in vivo tests.
- Immunotoxicity: May inhibit the immune system after prolonged or high-dose exposure.

SECTION 12: Ecological Information

12.1 **Toxicity**: Harmful to aquatic organisms; Zebrafish LC_{50} (96h) = 3.5 mg/L; Daphnia EC_{50} (48h) = 2.7 mg/L.12.2 **Persistence and Degradability**: Low biodegradability (BOD_5 /COD <0.2); persists in aquatic and soil environments for more than 6 months.12.3 **Bioaccumulative Potential**: High bioaccumulation factor (BCF >1500) in aquatic organisms, easy to accumulate in fatty tissues and disrupt endocrine system.12.4 **Mobility in Soil**: Low mobility; binds strongly to soil organic matter and is not easy to migrate with groundwater.12.5 **PBT and vPvB Assessment**: Classified as vPvB (very persistent, very bioaccumulative) based on test data.12.6 **Other Adverse Effects**: Disrupts the endocrine system of aquatic organisms, may cause reproductive dysfunction, immune system inhibition and population decline of sensitive aquatic species.

SECTION 13: Disposal Considerations

13.1 **Waste Treatment Methods**

- Product Waste: Do not discharge to the environment. Dispose of the unused product and contaminated waste to a licensed hazardous waste treatment facility in accordance with local, national and international regulations.
- Packaging Waste: Rinse the empty brown glass packaging with a small amount of ethanol, collect the rinse liquid as hazardous waste; dispose of the empty packaging as hazardous waste after drying.
- Spillage Residue: Collect all contaminated materials as hazardous waste, do not mix with non-hazardous waste; properly treat the cleaning waste to avoid environmental pollution.

13.2 **Disposal Notes**: Incineration must be carried out in a hazardous waste incinerator with a gas treatment system to remove toxic fumes; do not landfill the untreated waste.

SECTION 14: Transport Information

14.1 **UN Number**: UN 3077 (Environmentally hazardous substance, solid, n.o.s.)14.2 **UN Proper Shipping Name**: Environmentally hazardous substance, solid, n.o.s. (Budesonide)14.3 **Transport Hazard Class**: 9 (Miscellaneous dangerous goods)14.4 **Packaging Group**: III14.5 **Environmental Hazards**: Marine Pollutant (Yes); ADR/RID/IMDG/IATA: Class 9, environmentally hazardous.14.6 **Special Precautions for User**

- Transport the product in sealed brown glass packaging, use refrigerated transport at 2-8℃ with insulated and shockproof packaging.
- Avoid direct sunlight, high temperature, collision and rough handling during transport; the transport temperature must not exceed 25℃ for a long time.
- Do not transport with food, beverages, aquatic products, medical supplies, non-hazardous goods and strong oxidizing agents.
- Accompany with complete transport documents indicating the UN number, hazard class, refrigerated transport requirements and emergency contact information.

14.7 **IATA Restrictions**: Permitted for air transport (cargo only), limited quantity per package (≤5 kg); no transport on passenger aircraft; refrigerated air transport is required.

SECTION 15: Regulatory Information

15.1 **National Regulations (China)**

- Hazardous Chemical Safety Management Regulation: Classified as Class 9 hazardous chemical.
- Environmental Protection Law: Prohibited from discharge to water, soil and atmospheric environment.
- Pharmaceutical Administration Law: Regulated as a prescription pharmaceutical raw material, subject to special production, purchase and use licensing.
- Occupational Disease Prevention and Control Law: Require workplace exposure monitoring and employee health checks for long-term handlers.

15.2 **International Regulations**

- GHS Classification (Rev.9): Acute toxicity 4, Reproductive toxicity 1B, Target organ toxicity 2, Aquatic chronic 3.
- REACH (EU): Registered under REACH; listed in Annex XVII (restrictions on reproductive toxicants).
- TSCA (US): Listed on the TSCA Inventory; subject to EPA hazardous waste and environmental regulations.
- USP/EP: Complies with United States Pharmacopeia and European Pharmacopoeia standards for budesonide raw materials.
- IMDG Code: Class 9, UN 3077, Marine Pollutant, Packaging Group III.

SECTION 16: Other Information

- This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards, and is in line with USP/EP pharmaceutical specifications.
- The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product.
- This document is for professional use by trained personnel only; not for general consumer distribution or use.

- This is the first revision of this MSDS, issued on 15 FEB 2026; it will be updated in a timely manner with the latest scientific and regulatory information.

纳维盈医化科技
NEWAY SINOPHC TECH