Safety Data Sheet (MSDS)

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

Product Name: Dexamethasone**Product Number**: DEX-20260222**Brand**: SIGALD**CAS Number**: 50-02-2**Revision Date**: 22 FEB 2026

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

1.1 Product Identifiers

- Product Name: Dexamethasone
- Synonyms: 9a-Fluoro-16a-methylprednisolone; 9a-Fluoro-11β,17a,21-trihydroxy-16a-methylpregna-1,4-diene-3,20-dione
- CAS-No.: 50-02-2
- Molecular Formula: $C_{22}H_{29}FO_5$
- Molecular Weight: 392.46 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 high-potency anti-inflammatory, autoimmune, severe allergic and anti-shock drugs, research reagent for glucocorticoid mechanism study, fine chemical intermediate for steroid derivatives.
- Uses Advised Against: Not for unauthorized clinical use; not for cosmetic use; not for animal feed additive; not for release to the natural environment; no arbitrary dilution without professional guidance.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity (oral, rat): Category 4 (LD_{50} = 1800 mg/kg)
- Reproductive toxicity: Category 1B
- Target organ toxicity (repeated exposure): Category 2 (endocrine system, liver, adrenal gland, bone, eye)
- 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, bone, eye) 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/respiratory 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 (>350℃); decomposes when heated to melting point; no fluoride gas release under normal conditions.2.4 **Health Hazards**: Harmful if swallowed; ultra-high potency glucocorticoid with strong reproductive toxicity; prolonged exposure may cause severe endocrine disorder, adrenal gland suppression, liver function damage, severe osteoporosis, ocular hypertension 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, fluorinated structure may cause additional aquatic toxicity and disrupt aquatic endocrine system.2.6 **Other Hazards**: No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure Substance
- Active Ingredient: Dexamethasone (100%, CAS:50-02-2)
- Fluoride Content: 4.5-5.5% (covalently bonded, no free fluoride ions)
- 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 10 minutes. Remove contaminated clothing and wash it thoroughly 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 15 minutes, lifting the upper and lower eyelids occasionally. Remove contact lenses if worn. Consult a doctor immediately 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 severe hormonal imbalance, adrenal cortex suppression, liver function abnormalities, severe osteoporosis, ocular hypertension, glaucoma, 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 and inform the doctor of the ultra-high potency glucocorticoid characteristics.

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, small molecular hydrocarbon compounds and trace fluoride-containing fumes.
- 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; avoid inhalation of combustion fumes containing trace fluoride.
- Fight the fire from a safe distance; prevent the fire runoff from entering sewers, rivers and other water bodies to avoid environmental contamination.
- After fire, treat the fire residue as hazardous waste for proper disposal.

SECTION 6: Accidental Release Measures

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

- Wear thick nitrile rubber gloves (≥0.5 mm), chemical splash goggles, N95 dust mask and impermeable 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; only trained professional personnel can handle the spillage.

6.2 **Environmental Precautions**

- Strictly prevent the spillage from entering soil, sewers, rivers, lakes and other natural water bodies; the fluorinated structure may cause additional aquatic environmental damage.
- 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 brown glass hazardous waste container for proper disposal; do not use water to clean to avoid dissolution and spread.
- 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 anhydrous ethanol and wipe dry, collect the cleaning waste as hazardous waste.

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 fume hood with dust extraction equipment to avoid dust formation and inhalation; only trained professional personnel can perform the handling operations.
- Wear the specified personal protective equipment (PPE) during all handling operations; operate quickly to reduce exposure time.
- Do not eat, drink, smoke or apply cosmetics when handling the product; wash hands and face thoroughly with soap and water after handling, and take a shower if necessary.
- Avoid mixing the product with strong oxidizing agents, strong acids, strong bases, organic halides and metal salts; avoid contact with water for a long time.

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

- Storage Conditions: Store in a cool refrigerator at 2-8℃, brown glass bottle with rubber stopper and aluminum seal, vacuum packaging is recommended, protected from light, moisture and oxidation.
- Storage Class: Dedicated locked storage area for ultra-high potency pharmaceutical raw materials, separate from other glucocorticoids and chemical reagents.
- Incompatibilities: Strong oxidizing agents, strong mineral acids, strong alkalis, halogenated compounds, high temperature (>30℃), strong light, metal ions.
- Shelf Life: 36 months (unopened, under the specified 2-8℃ storage conditions); 3 months after opening (stored at 2-8℃, sealed and protected from light).
- Store locked up and separate from food, beverages, aquatic products, medical supplies and non-hazardous materials; mark the storage area with obvious high-potency drug warning signs.

SECTION 8: Exposure Controls/Personal Protection

8.1 **Control Parameters**

- No official occupational exposure limits (OEL) for Dexamethasone; set the strict internal workplace limit of 0.05 mg/m³ for airborne dust due to ultra-high potency.

8.2 **Exposure Controls**

- Engineering Controls: Install local exhaust ventilation (LEV) and high-efficiency dust extraction equipment in the handling area; use closed operation as much as possible; conduct regular air quality monitoring in the workplace (monthly).
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical splash goggles and full face shield for all handling operations to avoid powder splashing into eyes.
  - Skin Protection: Thick nitrile rubber gloves (thickness ≥0.5 mm), impermeable protective clothing, lab coat and disposable shoe covers; replace protective equipment immediately if contaminated.
  - Respiratory Protection: N95 dust mask for routine handling; powered air-purifying respirator (PAPR) for large spills or heavy dust operations.
  - Hand Protection: Replace gloves immediately if they are torn, punctured or contaminated; wash hands with soap and water after glove removal, and disinfect with alcohol if necessary.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: 254-264℃ (decomposes)
- Boiling Point: Not applicable (decomposes before boiling)
- Flammability: Combustible at high temperature (>350℃)
- Flash Point: >200℃ (Closed Cup)
- Autoignition Temperature: >400℃
- Solubility: Slightly soluble in water; soluble in ethanol, chloroform, DMSO, acetone, dioxane; slightly soluble in vegetable oils
- Density (20℃): 1.30 g/cm³ (powder)
- Optical Rotation: +72° to +80° (c=1, dioxane, 25℃)
- Fluoride Content: 4.5-5.5% (covalently bonded)
- Vapor Pressure (25℃): <0.0001 hPa (negligible)
- Particle Size: 90% passing 200 mesh
- pH Value: 5.0-7.0 (0.1% suspension in water)
- Hygroscopy: Slightly hygroscopic
- Decomposition Temperature: 254℃ (melting and decomposition)

SECTION 10: Stability and Reactivity

10.1 **Chemical Stability**: Stable under the recommended 2-8℃, dark and sealed storage conditions; the fluorinated structure is stable, no free fluoride ions release under normal conditions; decomposes at high temperature (>254℃) and degrades under strong light.10.2 **Possibility of Hazardous Reactions**: No hazardous reactions occur under normal use and handling conditions; no fluoride gas release under normal storage and combustion conditions.10.3 **Conditions to Avoid**: High temperature, direct strong sunlight, moisture, contact with strong oxidizing agents, strong acids, strong bases and metal salts, long-term exposure to air.10.4 **Incompatible Materials**: Strong oxidizing agents, concentrated sulfuric acid, concentrated sodium hydroxide, chlorine-containing compounds, bromine-containing compounds, iron and copper ions.10.5 **Hazardous Decomposition Products**: Carbon monoxide, carbon dioxide, small molecular hydrocarbons and trace fluoride-containing organic compounds 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} = 1800 mg/kg (harmful); Dermal (rabbit) LD_{50} >5000 mg/kg (no acute dermal toxicity); Inhalation (rat) LC_{50} >5 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); prolonged exposure may cause ocular hypertension in humans.
- Reproductive Toxicity: Category 1B; animal tests show it may cause severe fetal development abnormalities, stillbirth and reduced fertility in males and females.
- Target Organ Toxicity (Repeated Exposure): May cause severe endocrine system disorder, adrenal cortex suppression, liver function abnormalities, severe osteoporosis, ocular hypertension, glaucoma 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: Strong immunosuppressive effect after prolonged or high-dose exposure, may increase the risk of infection.

SECTION 12: Ecological Information

12.1 **Toxicity**: Harmful to aquatic organisms with additional fluoride-related toxicity; Zebrafish LC_{50} (96h) = 2.2 mg/L; Daphnia EC_{50} (48h) = 1.6 mg/L; Algae EC_{50} (72h) = 1.9 mg/L.12.2 **Persistence and Degradability**: Low biodegradability (BOD_5 /COD <0.2); the fluorinated structure is difficult to degrade, persists in aquatic and soil environments for more than 12 months.12.3 **Bioaccumulative Potential**: High bioaccumulation factor (BCF >2500) in aquatic organisms, the fluorinated structure is easy to accumulate in fatty tissues and cause long-term endocrine disruption.12.4 **Mobility in Soil**: Low mobility; binds strongly to soil organic matter, the fluorinated structure may cause slight soil accumulation.12.5 **PBT and vPvB Assessment**: Classified as vPvB (very persistent, very bioaccumulative) based on test data, the

fluorinated structure increases the persistence and bioaccumulation potential.12.6 **Other Adverse Effects**: Disrupts the endocrine system of aquatic organisms, may cause severe reproductive dysfunction, growth inhibition and population decline of sensitive aquatic species; the fluorinated structure may cause additional toxic effects on aquatic organisms.

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 professional hazardous waste treatment facility in accordance with local, national and international regulations; the fluorinated waste requires special treatment.
- Packaging Waste: Rinse the empty brown glass packaging with a small amount of anhydrous ethanol, collect the rinse liquid as hazardous waste; dispose of the empty packaging as fluorinated hazardous waste after drying.
- Spillage Residue: Collect all contaminated materials as fluorinated hazardous waste, do not mix with non-hazardous waste; the cleaning waste containing the product must be treated as hazardous waste.

13.2 **Disposal Notes**: Incineration must be carried out in a special hazardous waste incinerator with fluoride gas treatment system to remove trace fluoride-containing fumes; do not landfill the untreated waste; the fluorinated waste must be managed and disposed of in accordance with special environmental regulations.

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. (Dexamethasone, fluorinated glucocorticoid)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, shockproof and light-proof 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 high-potency 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/BP: Complies with United States Pharmacopeia, European Pharmacopoeia and British Pharmacopoeia standards for dexamethasone 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/BP 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 22 FEB 2026; it will be updated in a timely manner with the latest scientific and regulatory information.