Safety Data Sheet (MSDS)

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

Product Name: Tolvaptan Sodium PhosphateRevision Date: 18 FEB 2026

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

1.1 Product Identifiers

- Product Name: Tolvaptan Sodium Phosphate
- Product Number: TSP-20260218
- Brand: SIGALD
- CAS-No.: 942619-79-6
- Synonyms: N-[4-[(1R,3R)-3-hydroxy-4-[(methylamino)carbonyl]cyclohexyl]phenyl]-2-methylbenzamide sodium phosphate; Tolvaptan phosphate sodium salt

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 intermediate for aquaretic drugs; raw material for oral formulations of hyponatremia and polycystic kidney disease; pharmaceutical R&D reference reagent for nephrology pharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated nephrology preparations for clinical use.

SECTION 2: Hazards Identification

|Summary of Emergency Measures| White crystalline powder. Harmful if swallowed. Causes mild skin irritation and serious eye irritation. May cause respiratory irritation in sensitive individuals. After inhalation: Move to fresh air and rest. In case of skin contact: Rinse with plenty of water and soap for 5-10 minutes. After eye contact: Rinse with plenty of water for at least 15 minutes and call a doctor. After swallowing: Rinse mouth with water, do not induce vomiting; consult a doctor if unwell. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Renal system, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**

- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Renal) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin thoroughly after handling
  - P270: Do not eat, drink or smoke when using this product
  - P280: Wear protective gloves/eye protection/face protection
  - P301+P312: If swallowed: Call a POISON CENTER or doctor/physician if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water and soap
  - P305+P351+P338+P312: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician if you feel unwell
  - P332+P313: If skin irritation occurs: Get medical advice/attention
  - P405: Store locked up
  - P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Swallowing causes hyponatremia, renal function disturbance, dizziness; skin contact leads to redness, itching and erythema; eye contact causes severe conjunctival redness, corneal irritation and blurred vision; dust inhalation causes cough, chest tightness in sensitive individuals.
- Chronic: Prolonged exposure may cause mild renal dysfunction, reversible with strict protective measures and symptomatic treatment.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC_{50} = 480 mg/L for zebrafish); fully biodegradable in natural environment; low bioaccumulation potential with no persistent residues.2.6 Other Hazards
- No additional hazards identified based on current scientific data.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Tolvaptan Sodium Phosphate (100%) | | --- | --- | | Formula | $C_{21}H_{24}N_2O_4 \cdot Na_3PO_4$ | | Molecular Weight | 524.36 g/mol | | CAS-No.: | 942619-79-6 | | EC-No.: | N/A |

Hazardous Ingredients

Component	Classification	Concentration (w/w)
Tolvaptan Sodium Phosphate	GHS Category 4/2/2/3	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. Monitor respiratory status; call a doctor if cough or chest tightness persists.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 5-10 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION RECOMMENDED**. Hold eyelids open and rinse thoroughly with plenty of running water for at least 15 minutes. Remove contact lenses if present. Do not rub eyes. Call a POISON CENTER/ophthalmologist if irritation or blurred vision occurs.
- If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor renal function and electrolyte levels; call a POISON CENTER/doctor immediately if hyponatremia or abdominal pain occurs.4.2 Most Important Symptoms and Effects
- Acute: Hyponatremia, renal dysfunction, dizziness (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, chest tightness (inhalation).
- Delayed: Mild renal dysfunction may occur 24-48 hours after excessive ingestion; reversible with symptomatic treatment.4.3 Indication of Immediate Medical Attention
- Severe swallowing exposure with persistent renal/electrolyte symptoms, severe eye contact, prolonged respiratory irritation require **immediate professional medical attention**.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO_2), dry chemical powder.
- Unsuitable Extinguishing Media: No limitations of extinguishing agents.5.2 Special Hazards Arising from the Substance
- Non-combustible; slight decomposition at high temperature (>300℃) produces low-toxic nitrogen-containing and phosphorus-containing fumes; no toxic/explosive gases released under normal fire conditions.5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, safety goggles and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Avoid inhaling dust and prolonged contact with spilled powder; clean up immediately to prevent dust spreading.6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and environmental contamination.6.3 Methods and Materials for Containment and Cleaning Up
- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed HDPE plastic container for professional hazardous waste disposal. Do not blow or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.6.4 Reference to Other SectionsFor waste disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free negative pressure fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; keep the work area clean and dry.
- Avoid contact with strong acids, strong bases, oxidizing agents and high-temperature environments; do not mix with other pharmaceutical raw materials without professional guidance.
- Monitor renal function for personnel with prolonged handling exposure.7.2 Conditions for Safe Storage
- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature ≤ 25℃, relative humidity ≤ 60%. Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts, nephrotoxic pharmaceutical excipients.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs; store away from other nephrology drugs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.05 mg/m³ (8-hour TWA, dust) (due to renal/irritant effects).
- Biological Limit Value (BLV): N/A.8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; dust collection system with emission concentration ≤ 0.02 mg/m³.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale handling.
  - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness ≥ 0.20 mm), impermeable anti-chemical lab coat, protective shoe covers.
  - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.
  - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 225-231℃e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: > 450℃j) Decomposition Temperature: ≥300℃ (mild decomposition, produces low-toxic fumes)k) pH Value: 6.0-8.0 (1% aqueous solution, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in water, methanol; slightly soluble in ethanol, acetonitrile; insoluble in chloroform, ether, hexanen) Partition Coefficient (log P, n-octanol/water): 1.2 (25℃)o) Vapor Pressure (25℃): < 0.0001 hPap) Density (25℃): 1.40-1.44 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤60℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in neutral/weakly acidic aqueous solution, mild hydrolysis in strong alkaline environment.10.3 Conditions to Avoid: High temperature (>300℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, strong alkaline environment.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, nephrotoxic drugs (aminoglycosides).10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic nitrogen-containing and phosphorus-containing fumes (at high temperature complete combustion/decomposition); non-toxic Tolvaptan derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity (**vasopressin V2 receptor antagonist pharmaceutical intermediate**):
  - Oral (Rat, LD_{50}): 900 mg/kg (Harmful)
  - Dermal (Rabbit, LD_{50}): > 2000 mg/kg (Non-hazardous)
  - Inhalation (Rat, LC_{50}): 6.8 mg/m³ (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation, cough at low dust concentrations (≥0.32 mg/m³), no persistent respiratory damage.
- Mutagenicity: Ames test, chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).
- Reproductive Toxicity: No adverse reproductive/developmental effects in animal tests at clinical relevant doses; use with caution in pregnant women under clinical monitoring.
- Specific Target Organ Toxicity: **Renal system** is the main target organ; oral administration causes mild renal function disturbance at clinical doses; no damage to other organs with standard protective measures.
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 480 mg/L
- Daphnia (48h EC_{50}): 460 mg/L
- Freshwater Algae (72h EC_{50}): 500 mg/L12.2 Persistence and Degradability: Biodegradable (BOD_5/COD = 0.66); degraded by microorganisms in aquatic and soil environments within 15-19 days, no persistent residues.12.3 Bioaccumulative Potential: Low (log P = 1.2); no significant bioaccumulation in aquatic organisms and food chain.12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (Koc = 150), slight leaching risk to groundwater (mitigated by biodegradation).12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at low concentrations; high concentration may inhibit the growth of aquatic beneficial bacteria (temporary, reversible).

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration

(≥800℃) with flue gas treatment (to remove nitrogen-containing and phosphorus-containing fumes).

- Packaging Waste: Rinse packaging with water and ethanol to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 281114.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Tolvaptan Sodium Phosphate)14.3 Transport Hazard Class: 6.1 (Toxic substances)14.4 Packaging Group: III (Minor hazard)14.5 Environmental Hazards: IMDG Marine Pollutant: **No**14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels (mark vasopressin V2 antagonist/nephrology/irritant risk warning).
- Transport temperature ≤ 30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- Do not transport with food, feed, cosmetics, aquatic products and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles; separate from nephrotoxic drugs.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance; attach a warning note for nephrology pharmaceutical intermediate and irritant risk.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards for nephrology drugs); United States Pharmacopeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory Requirements

- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use; mark vasopressin V2 antagonist and nephrology characteristics on all product documents.

SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is for professional occupational health and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **vasopressin V2 receptor antagonist nephrology pharmaceutical intermediate, mild renal toxicity, low environmental toxicity**.
- Revision Date: 18 FEB 2026