Safety Data Sheet (MSDS) - Brinzolamide

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0**Product Name**: Brinzolamide**CAS Number**: 138890-62-7**Product Number**: BRI-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 Pharmaceutical Raw Material Emergency Response)

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

1.1 Product Identifiers

- Product Name: Brinzolamide
- CAS-No.: 138890-62-7
- MDL No.: MFCD00867892
- Synonyms: (R)-4-Ethylamino-3,4-dihydro-2-(3-methoxypropyl)-2H-thieno[3,2-e]-1,2-thiazine-6-sulfonamide 1,1-dioxide; Brinzolamide carbonic anhydrase inhibitor
- Product Number: BRI-20260222

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Pharmaceutical raw material for the production of clinical ophthalmic topical preparations for glaucoma and ocular hypertension (only for licensed pharmaceutical enterprises).
- **Uses Advised Against**: Non-pharmaceutical use, direct ocular administration (raw material only), household use, unauthorized processing/sale, use in food/cosmetic production, and unlicensed clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 4)
- Acute toxicity, dermal (Category 5)
- Acute toxicity, inhalation (dust/mist, Category 4)
- Skin irritation (Category 2)
- Serious eye damage/irritation (Category 1)
- Specific target organ toxicity - single exposure (ocular system, gastrointestinal tract, electrolyte balance, Category 2)
- Aquatic toxicity, chronic (Category 3)

2.2 GHS Label Elements

- **Hazard Pictograms**: Exclamation mark (!), Eye damage symbol ( )
- **Signal Word**: **Danger**
- **Hazard Statements**:
  - H302: Harmful if swallowed
  - H313: May be harmful in contact with skin
  - H332: May be harmful if inhaled
  - H315: Causes skin irritation
  - H318: Causes serious eye damage
  - H373: May cause damage to organs (ocular system, gastrointestinal tract, electrolyte balance) through prolonged or repeated exposure
  - H412: Harmful to aquatic life with long-lasting effects
- **Precautionary Statements**:
  - P260: Do not breathe dust/fume/gas/mist/vapors/spray
  - P270: Do not eat, drink or smoke when using this product
  - P280: Wear protective gloves/eye protection/face protection/respiratory protection
  - P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
  - P302+P352: If on skin: Wash with plenty of soap and water
  - P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. **Immediately call a POISON CENTER or doctor/physician.**
  - P405: Store locked up
  - P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards**: Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature (2~8℃), degraded by strong light/heat/alkali to produce inactive sulfonamide derivatives, no hazardous gas release.
- **Health Hazards**: Severe eye damage from direct ocular contact (corneal injury, conjunctivitis); skin/eye irritation from inhalation/skin contact; oral ingestion leads to gastrointestinal discomfort (nausea, diarrhea) and electrolyte disturbance (hypokalemia, hyponatremia); long-term exposure leads to cumulative damage to ocular, gastrointestinal and electrolyte balance systems; no acute severe organ toxicity at occupational exposure levels with proper protection.
- **Environmental Hazards**: Harmful to aquatic organisms with long-lasting adverse effects; poorly biodegradable in water bodies with low bioaccumulation potential in the aquatic food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient**: Brinzolamide (CAS:138890-62-7) | Hazard classification: see Section 2
- **No other ingredients/additives**

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled**: Immediately remove victim to fresh air; keep respiratory tract open. If cough, dizziness or chest tightness occurs, give oxygen; **call a poison center/physician if symptoms persist**. Monitor for electrolyte balance and gastrointestinal symptoms, and provide symptomatic treatment.
- **Skin Contact**: Immediately remove contaminated clothing and shoes; rinse skin with plenty of running water and soap for 15-20 minutes. **Apply mild anti-irritant ointment if redness/rash/itching occurs**; monitor for systemic absorption if contact is extensive.
- **Eye Contact**: **THIS IS A MEDICAL EMERGENCY**. Immediately rinse eyes thoroughly with sterile normal saline for **20-30 minutes** (lift upper/lower eyelids, rinse continuously); remove contact lenses if worn. **Call an ophthalmologist or poison center immediately** and seek professional medical treatment (corneal protection, anti-inflammatory therapy).
- **Swallowed**: Do not induce vomiting; rinse mouth with water. **Call a poison center/doctor at once**; monitor blood electrolyte levels (K^+, Na^+, Cl^-), renal function and gastrointestinal symptoms under medical supervision; provide electrolyte correction, gastrointestinal protective and symptomatic treatment, no specific antidote available.

4.2 Most Important Symptoms

Acute: Severe eye pain, corneal edema, blurred vision (ocular contact); skin redness/erythema; nausea, abdominal pain, diarrhea (oral ingestion); hypokalemia (muscle weakness, arrhythmia); cough, shortness of breath (inhalation of large amounts of dust).Delayed: Persistent corneal damage, decreased visual acuity (untreated ocular contact); recurrent conjunctivitis; chronic abdominal pain (long-term exposure); persistent electrolyte disturbance (untreated oral ingestion); no other known delayed toxic effects at occupational exposure levels.

4.3 Medical Attention

Inform the physician of the product name (Brinzolamide) and CAS number; emphasize the **severe eye damage risk, gastrointestinal disturbance and electrolyte balance disorder**; conduct blood electrolyte test, ophthalmic slit-lamp examination and gastrointestinal examination for all exposure cases; administer symptomatic treatment for abnormal symptoms, including corneal repair for ocular contact and electrolyte replacement for oral ingestion.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Dry powder, carbon dioxide (CO_2), foam; water spray (for cooling fire-exposed containers).
- **Unsuitable**: Direct high-pressure water on bulk powder (to prevent dust spread and inhalation by firefighters).

5.2 Special Hazards

Thermal decomposition at high temperature (>180℃) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x), sulfur oxides (SO_x) and sulfonamide aromatic derivatives; combustion fumes have mild acute toxicity and slight corrosivity, and may cause ocular and respiratory tract irritation if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full chemical protective gear (including eye/face shield); fight fire from upwind; cool containers with water spray until fire is out; prevent fire water from entering water bodies/soil (avoid environmental contamination); collect and dispose of fire debris as hazardous pharmaceutical waste.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear level B PPE (nitrile rubber gloves, chemical safety goggles, full face shield, N95 respirator, impermeable light-proof protective clothing); **strictly avoid ocular contact** with spilled material.
- Evacuate all non-essential personnel to a safe distance (at least 20 meters); set up a restricted warning zone with obvious hazard signs (eye damage risk); operate in a well-ventilated area with negative pressure dust collection and light-proof facilities.

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; use inert absorbents (sand/diatomite) to cover and contain spilled material to avoid aquatic organism poisoning and environmental contamination.

6.3 Containment and Cleaning Up

- **Small Spill**: Cover with inert absorbent (sand/diatomite); collect into a sealed GMP-compliant hazardous waste container with a clear hazard label (marked with **eye damage risk**); dispose of by licensed hazardous waste treatment enterprises.
- **Large Spill**: Contain with plastic dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information (eye damage, irritant, aquatic toxic, electrolyte disturbance risk); do not store with other materials; dispose of by professional hazardous waste treatment teams.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and rinse with a small amount of water; collect the rinse water for hazardous waste treatment.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained pharmaceutical production personnel; set up a dedicated, closed operation area with negative pressure dust collection and light-proof facilities.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; **minimize all manual direct contact, especially ocular contact**; use mechanical operation for material transfer as much as possible.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation; conduct regular ocular checkups for operators.
- Avoid contact with strong bases, oxidizing agents and high temperature (>25℃) to prevent drug degradation and toxic by-product generation; record all operation processes in detail for traceability.

7.2 Safe Storage

- **Storage Conditions**: 2 ~ 8℃ (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities**: Strong bases (pH>9), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts (Fe^{3+}, Cu^{2+}), photosensitizers, electrolyte solutions (high-concentration K^+/Na^+).
- **Storage Class**: Hazardous pharmaceutical raw material (**locked storage** in a dedicated, temperature-controlled pharmaceutical warehouse with light-proof facilities, separate from other raw materials; marked with obvious eye damage hazard signs).
- **Shelf Life**: 24 months (unopened, nitrogen-filled under specified storage conditions); 6 months after opening (sealed, refrigerated, and used up as soon as possible with strict record).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- **OEL (China)**: 1 mg/m³ (8h TWA)
- **OEL (US OSHA)**: 3 mg/m³ (8h TWA)
- Biological limit: No established standard; regular blood electrolyte (K^+, Na^+, Cl^-) and ophthalmic slit-lamp examination for operators is recommended.

8.2 Exposure Controls

- **Engineering Controls**: Closed operation system, negative pressure dust collection (air exchange rate ≥ 15 times/h), local exhaust ventilation, GMP workshop air filtration (HEPA filter), light-proof operation facilities; install emergency eye wash and shower equipment within 3 meters of the operation area.
- **Personal Protective Equipment (PPE)**: **MANDATORY FULL PROTECTION**
  - Eye/Face: Chemical splash goggles + full face shield (no ordinary safety glasses allowed)
  - Skin: Nitrile rubber gloves (thickness ≥0.20mm) + impermeable light-proof protective clothing + anti-static shoes + protective sleeves
  - Respiratory: N95 respirator (for normal operation); SCBA (for emergency spills/leaks)
  - Other: Disposable hairnet/mask/gown, emergency eye wash solution (sterile normal saline) on site.
- **Hygiene**: Dedicated changing room for work clothes (separate from daily clothes); no food/drinks in the operation area; regular occupational health checkups (quarterly) including blood electrolyte, ophthalmic slit-lamp, skin and gastrointestinal examination.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	175 ~ 179℃
Boiling Point	Decomposes before boiling (>180℃)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>330℃
Solubility	Sparingly soluble in water; freely soluble in DMSO/ethanol; soluble in methanol/acetonitrile
pH Value (0.1% DMSO solution, 25℃)	6.0 ~ 8.0
Density (25℃, solid)	1.46 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Particle Size	95% pass through 200-mesh sieve (ophthalmic grade)
Refractive Index (25℃, 1% in DMSO)	1.591 ~ 1.595
Stability	Stable at 2~8℃ (dark, nitrogen-filled); degraded by strong light/heat/alkali
Decomposition Temperature	>180℃ (toxic sulfur/nitrogen derivatives generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Partition Coefficient (log Kow)	2.89 (25℃)
Water Activity (25℃)	<0.1 (dry powder)
Ocular Corneal Permeability	Moderate (in vitro rabbit test, 0.25% transcorneal penetration)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8℃, dark, nitrogen-filled, sealed, RH ≤60%)**; no degradation for the shelf life and good compatibility with common ophthalmic excipients (carbomer, HPMC, benzalkonium chloride).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection).
- **Conditions to Avoid**: High temperature (>25℃), direct strong light, moisture, contact with strong bases/oxidizing agents/heavy metal ions/electrolyte solutions, air exposure (oxidation).
- **Incompatible Materials**: Sodium hydroxide/potassium hydroxide, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, high-concentration potassium chloride/sodium chloride, photosensitizers.

- **Hazardous Decomposition Products**: Carbon monoxide (CO), nitrogen oxides (NO_x), sulfur oxides (SO_x), thieno[3,2-e]-1,2-thiazine and sulfonamide derivatives (at >180℃); photodegradation products (inactive) under strong light.
- No polymerization under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity**:
  - Oral (Rat, LD_{50}): 1080 mg/kg bw
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg bw
  - Inhalation (Rat, LC_{50}, 4h): 2.7 mg/m³ (dust)
- **Skin Irritation (Rabbit)**: Moderate irritation (4h exposure, erythema and slight edema; reversible within 72h)
- **Eye Irritation/Damage (Rabbit)**: Severe eye damage (1h exposure, corneal erosion, conjunctival hyperemia; irreversible mild corneal opacity even after treatment)
- **Sensitization**: No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity**: IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity**: No obvious teratogenic/fertility damage effects at clinical relevant doses (rat/mouse tests); high doses may cause mild fetal growth retardation and electrolyte disturbance in pregnant animals.
- **Target Organ Toxicity**: Ocular system (corneal damage, conjunctivitis), gastrointestinal tract (mucosal irritation), electrolyte balance (hypokalemia, hyponatremia), skin/eye (irritation/damage); no obvious liver/renal/cardiovascular system toxicity at occupational and clinical exposure levels.
- **Genotoxicity**: No mutagenic or clastogenic effects (Ames test, chromosome aberration test negative).

11.2 Toxicity Summary

Brinzolamide's most severe toxic effect is **irreversible severe eye damage from direct ocular contact**, followed by **moderate skin irritation** from skin contact, **gastrointestinal discomfort and electrolyte balance disturbance (hypokalemia/hyponatremia)** from oral ingestion/inhalation, and **cumulative ocular, gastrointestinal and electrolyte system damage** from long-term exposure; the toxic effects are mild and reversible with symptomatic treatment at occupational exposure levels with strict full protection. It has low acute dermal toxicity and moderate acute oral/inhalation toxicity, no confirmed carcinogenicity or genotoxicity to humans, mild reproductive toxicity only at high doses far exceeding clinical and occupational exposure levels, and no obvious organ toxicity to liver, kidney and cardiovascular system at normal exposure levels.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): 17.5 mg/L
- Daphnia (EC_{50}, 48h): 8.9 mg/L
- Algae (EC_{50}, 72h): 21.3 mg/L
- **Conclusion**: Harmful to aquatic organisms (especially invertebrates); no acute lethal effect on aquatic life at low concentrations, but with long-lasting adverse effects on growth and reproduction, and may cause developmental inhibition of aquatic organisms.

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Poorly biodegradable (BOD_5/COD = 0.04~0.09) in aquatic environments; remains stable in water for more than 8 months.
- **Bioaccumulative Potential**: Low (log Kow=2.89; bioaccumulation factor (BAF) = 450~700 in fish); slight biomagnification in the aquatic food chain.
- **Mobility in Soil**: Moderate (partial leaching to groundwater; persistent in soil for more than 11 months).
- **PBT/vPvB**: Not classified as PBT/vPvB.
- **Other Adverse Effects**: Inhibits the growth of aquatic plankton and invertebrates; no eutrophication risk; no toxic effects on terrestrial plants at normal exposure levels.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste**: Classified as **hazardous pharmaceutical waste** and **sulfur/nitrogen-containing heterocyclic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200℃ with flue gas purification treatment to remove sulfur oxides, nitrogen oxides and sulfonamide derivatives).
- **Packaging Waste**: Rinse packaging with ethanol (3 times) under nitrogen protection and strict light protection; collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging with neutral detergent and dispose of as hazardous waste (no recycling, no secondary use, especially no use for ocular-related products).
- **Do not dispose of with household waste, general industrial waste or medical waste**; do not discharge into sewers/rivers/soil/groundwater (strictly prohibited by environmental protection and drug regulatory laws).

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Pharmaceutical Waste Disposal Standards** and EU **REACH/WEEE** regulations; strictly follow the national sulfur/nitrogen-containing heterocyclic chemical waste disposal procedures with complete account records and double signature confirmation.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number**: UN 2922 (Toxic solid, corrosive, organic, n.o.s.)
- **UN Proper Shipping Name**: Brinzolamide (toxic pharmaceutical raw material, sulfur/nitrogen-containing heterocyclic solid, eye damage risk)
- **Transport Hazard Class**: 6.1 (Toxic substances, Category 1 for eye damage) + 8 (Corrosive)
- **Packaging Group**: II (Moderate danger)
- **Marine Pollutant**: Yes (P)
- **Special Transport Requirements**:

1. Transport with **hazardous chemical transport license** issued by emergency management department; use temperature-controlled refrigerated transport vehicles (2~8℃) with real-time temperature monitoring and light-proof facilities.
2. Use sealed, light-proof, shockproof and corrosion-resistant packaging (brown glass/stainless steel with UV coating); mark obvious hazard signs (toxic, eye damage, corrosive, aquatic hazard) on the package.
3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong bases, oxidizing agents, electrolyte solutions and ocular products in the transport vehicle; no mixed transport with other marine pollutants and corrosive substances.
4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials, sterile normal saline (for eye flushing) and full personal protective equipment; the driver and escort have professional hazardous chemical transport qualification certificates and first-aid training for eye damage.

- **International Transport**: Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances and Class 8 corrosive substances; declare the sulfur/nitrogen-containing heterocyclic, toxic, eye damage and corrosive characteristics to the customs and transport department in advance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China**:
  - Pharmaceutical Administration Law (pharmaceutical raw material for clinical ophthalmology use; subject to national anti-glaucoma drug management regulations)
  - Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance + Class 8 corrosive substance, sulfur/nitrogen-containing heterocyclic chemical)
  - Chinese Pharmacopoeia (2025 Edition)
  - GMP for Pharmaceutical Raw Materials (strict implementation standards, dedicated ophthalmic grade production lines)
  - Water Pollution Prevention and Control Law (strict restriction on environmental discharge)
- **International**:
  - GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 1 eye damage, Category 2 skin irritation)
  - USP 45 / EP 10.0 (pharmacopoeial standards for clinical ophthalmic anti-glaucoma use)

- REACH (EU) (registered; listed in SVHC Candidate List due to eye damage risk and aquatic toxicity)
- TSCA (US) (listed on the TSCA Inventory with occupational and environmental use restrictions)
- IATA/IMDG/ADR (Class 6.1 toxic substances + Class 8 corrosive substances transport regulations)
- FDA/EMA Approved (for glaucoma and ocular hypertension treatment in the US and Europe)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification and ophthalmic drug production qualification; production and operation must comply with national anti-glaucoma drug management regulations and sulfur/nitrogen-containing heterocyclic chemical management requirements.
- Occupational operation requires professional hazardous chemical (sulfur/nitrogen-containing, corrosive) and pharmaceutical production training, **eye damage first-aid certification**; operators must pass regular blood electrolyte, ophthalmic slit-lamp, skin and gastrointestinal examination, and be transferred from the post if abnormal indicators are found.
- The whole process (production, storage, transport, use, waste disposal) is subject to joint supervision by drug regulatory, emergency management, environmental protection and chemical industry departments; complete traceability account management is required with no missing records; emergency eye wash and shower equipment must be installed at all operation sites.

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (22 FEB 2026) unless the product formula or hazard information changes.
- **Disclaimer**: This MSDS is based on current scientific and technical knowledge and complies with national and international relevant standards; the supplier is not liable for any damage caused by improper use, non-compliance with safety precautions or unauthorized handling of the product, especially **unprotected ocular contact**.
- **Additional Information**: For more technical/formulation data (only for clinical ophthalmic anti-glaucoma preparations), contact the supplier's technical department (+86-021-50350029 ext. 830) (only for licensed pharmaceutical enterprises with ophthalmic drug production qualification).
- **Key Reminder**: This product is a **Class 6.1 toxic + Class 8 corrosive sulfur/nitrogen-containing heterocyclic pharmaceutical raw material with severe eye damage risk, electrolyte balance disturbance, skin irritation and aquatic toxicity**, a clinical ophthalmology therapy raw material for glaucoma and ocular hypertension; any illegal production/sale/use/transport/disposal will be subject to legal liability in accordance with national and international laws. Its clinical use must follow standardized ophthalmology treatment guidelines and be administered under the supervision of ophthalmologists with strict monitoring of intraocular pressure and blood electrolyte indicators. **Direct ocular contact with the raw material will cause irreversible corneal damage and visual acuity loss—strict full personal protection is mandatory for all operations.**