



NEWAY SINOPHC TECH. LIMITED

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Safety Data Sheet (MSDS) - Bomeprazole

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0
Product Name: Bomeprazole
CAS Number: 73590-58-6
Product Number: BOM-20260225
Brand: SIGALD
Revision Date: 25 FEB 2026
Supplier: NEWAY SINOPHC TECH. LIMITED
Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE
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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Bomeprazole
- CAS-No.: 73590-58-6
- MDL No.: MFCD00867396
- Synonyms: 5-Methoxy-2-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl-1H-benzimidazole; Bomeprazole PPI
- Product Number: BOM-20260225

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical oral preparations for acid-related gastrointestinal diseases (only for licensed pharmaceutical enterprises).
- **Uses Advised Against:** Non-pharmaceutical use, direct clinical 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 irritation (Category 2)
- Specific target organ toxicity - single exposure (gastrointestinal tract, hepatobiliary system, Category 2)
- Aquatic toxicity, chronic (Category 3)

2.2 GHS Label Elements

- **Hazard Pictograms:** Exclamation mark (!)
- **Signal Word:** Warning
- **Hazard Statements:**
 - H302: Harmful if swallowed
 - H313: May be harmful in contact with skin
 - H332: May be harmful if inhaled
 - H315: Causes skin irritation
 - H319: Causes serious eye irritation
 - H373: May cause damage to organs (gastrointestinal tract, hepatobiliary system) 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: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 - P405: Store locked up
 - P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary



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- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature (2~8°C), degraded by strong light/heat/alkali to produce inactive benzimidazole derivatives, no hazardous gas release.
- **Health Hazards:** Inhalation/skin contact causes skin/eye irritation; oral ingestion leads to mild gastrointestinal discomfort (nausea, diarrhea) and potential mild hepatobiliary system disturbance; long-term exposure leads to cumulative damage to gastrointestinal and hepatobiliary 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:** Bomeprazole (CAS:73590-58-6) | 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 or dizziness occurs, give oxygen; **call a poison center/physician if symptoms persist.** Monitor for gastrointestinal and hepatobiliary 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:** Immediately rinse eyes thoroughly with plenty of sterile water for injection for 15-20 minutes (lift upper/lower eyelids); remove contact lenses if worn. **Consult an ophthalmologist immediately** even if no irritation is felt initially.
- **Swallowed:** Do not induce vomiting; rinse mouth with water. **Call a poison center/doctor at once;** monitor gastrointestinal symptoms and liver function indicators under medical supervision; provide gastrointestinal protective and hepatoprotective symptomatic treatment, no specific antidote available.

4.2 Most Important Symptoms

Acute: Severe eye redness, tearing, blurred vision; skin redness/erythema; nausea, abdominal pain, diarrhea (oral ingestion); mild liver function index elevation (prolonged exposure); cough (inhalation of large amounts of dust). Delayed: Persistent gastrointestinal discomfort (untreated oral ingestion); recurrent conjunctivitis (untreated eye contact); mild cholestasis (long-term exposure); no other known delayed toxic effects at occupational exposure levels.

4.3 Medical Attention

Inform the physician of the product name (Bomeprazole) and CAS number; emphasize the **gastrointestinal/hepatobiliary system damage and local skin/eye irritation risk;** conduct gastrointestinal examination and liver function test for oral ingestion/inhalation cases; administer symptomatic treatment for abnormal symptoms, no specific medical intervention required for mild exposure.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Dry powder, carbon dioxide (CO₂), 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 (>160°C) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x) and benzimidazole aromatic derivatives; combustion fumes have mild acute toxicity and slight corrosivity, and may cause gastrointestinal and hepatobiliary irritation if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and standard chemical protective gear; 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); avoid any direct contact with spilled material, especially eye contact.
- Evacuate all non-essential personnel to a safe distance (at least 15 meters); set up a restricted warning zone with obvious hazard signs; 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; 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 (irritant, aquatic toxic, gastrointestinal/hepatobiliary system 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 manual direct contact with the product, especially eye contact.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation.
- Avoid contact with strong bases, oxidizing agents and high temperature (>25°C) 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°C (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities:** Strong bases (pH>9), oxidizing agents (H₂O₂, KMnO₄), heavy metal salts (Fe³⁺, Cu²⁺), photosensitizers.
- **Storage Class:** Hazardous pharmaceutical raw material (locked storage in a dedicated, temperature-controlled pharmaceutical warehouse with light-proof facilities, separate from other raw materials).
- **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):** 2 mg/m³ (8h TWA)
- **OEL (US OSHA):** 5 mg/m³ (8h TWA)
- Biological limit: No established standard; regular liver function and gastrointestinal examination for operators is recommended.

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, negative pressure dust collection (air exchange rate ≥ 12 times/h), local exhaust ventilation, GMP workshop air filtration (HEPA filter), light-proof operation facilities.
- **Personal Protective Equipment (PPE):**
 - Eye/Face: Chemical safety goggles + full face shield (mandatory for all operations)

- Skin: Nitrile rubber gloves (thickness $\geq 0.18\text{mm}$) + impermeable light-proof protective clothing + anti-static shoes
- Respiratory: N95 respirator (for normal operation); SCBA (for emergency spills/leaks)
- Other: Disposable hairnet/mask/gown, hand washing station with emergency eye wash equipment (within 5 meters of operation area).
- **Hygiene:** Dedicated changing room for work clothes (separate from daily clothes); no food/drinks in the operation area; regular occupational health checkups (half-yearly) including liver function, gastrointestinal, skin and ophthalmic examination.

SECTION 9: Physical and Chemical Properties

表格

| Property | Value |
|---|--|
| Physical State | White to off-white crystalline powder |
| Odor | Odorless |
| Melting Point | 156 ~ 160°C |
| Boiling Point | Decomposes before boiling (>160°C) |
| Flash Point | Non-flammable (no flash point) |
| Autoignition Temperature | >320°C |
| Solubility | Sparingly soluble in water; freely soluble in methanol/ethanol; soluble in acetonitrile/DMSO |
| pH Value (0.1% methanol solution, 25°C) | 5.0 ~ 7.0 |
| Density (25°C, solid) | 1.34 g/cm ³ |
| Vapor Pressure (25°C) | <0.0001 hPa (negligible) |
| Particle Size | 95% pass through 100-mesh sieve (pharmaceutical grade) |
| Refractive Index (25°C, 1% in CH ₃ OH) | 1.572 ~ 1.576 |
| Stability | Stable at 2~8°C (dark, nitrogen-filled); degraded by strong light/heat/alkali |
| Decomposition Temperature | >160°C (toxic nitrogen/benzimidazole derivatives generated) |
| Flammability | Non-flammable |
| Explosive Properties | Non-explosive |
| Partition Coefficient (log Kow) | 3.86 (25°C) |
| Water Activity (25°C) | <0.1 (dry powder) |
| Plasma Protein Binding Rate | ≈95% (in vitro, human plasma) |

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8°C, dark, nitrogen-filled, sealed)**; no degradation for the shelf life and good compatibility with common pharmaceutical excipients for oral solid formulations (microcrystalline cellulose, croscarmellose sodium, hypromellose).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection).
- **Conditions to Avoid:** High temperature (>25°C), direct strong light, moisture, contact with strong bases/oxidizing agents/heavy metal ions, air exposure (oxidation).
- **Incompatible Materials:** Sodium hydroxide/potassium hydroxide, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, photosensitizers.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), benzimidazole and pyridinyl derivatives (at >160°C); 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, LD₅₀): 1150 mg/kg bw
 - Dermal (Rabbit, LD₅₀): >2000 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 3.2 mg/m³ (dust)

- **Skin Irritation (Rabbit):** Moderate irritation (4h exposure, erythema and slight edema; reversible within 72h)
- **Eye Irritation (Rabbit):** Severe irritation (24h exposure, conjunctivitis, corneal redness; reversible within 7 days)
- **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 gastrointestinal disturbance in pregnant animals.
- **Target Organ Toxicity:** Gastrointestinal tract (mucosal irritation), hepatobiliary system (mild functional disturbance), skin/eye (irritation); no obvious kidney/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

Bomeprazole's main toxic effects are **severe eye irritation and moderate skin irritation** from direct contact, **gastrointestinal discomfort and mild hepatobiliary system disturbance** from oral ingestion/inhalation, and **cumulative gastrointestinal and hepatobiliary system damage** from long-term exposure; the toxic effects are mild and reversible with symptomatic treatment at occupational exposure levels with proper 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 kidney and cardiovascular system at normal exposure levels.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 19.8 mg/L
- Daphnia (EC₅₀, 48h): 10.5 mg/L
- Algae (EC₅₀, 72h): 24.2 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 (BOD₅/COD = 0.05~0.10) in aquatic environments; remains stable in water for more than 7 months.
- **Bioaccumulative Potential:** Low (log Kow=3.86; bioaccumulation factor (BAF) = 550~800 in fish); slight biomagnification in the aquatic food chain.
- **Mobility in Soil:** Moderate (partial leaching to groundwater; persistent in soil for more than 10 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 **nitrogen-containing heterocyclic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200°C with flue gas purification treatment to remove nitrogen oxides and benzimidazole derivatives).
- **Packaging Waste:** Rinse packaging with ethanol (3 times) under nitrogen 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).
- **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 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 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name:** Bomeprazole (toxic pharmaceutical raw material, nitrogen-containing heterocyclic solid)
- **Transport Hazard Class:** 6.1 (Toxic substances, Category 4)
- **Packaging Group:** III (Minor 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°C) with real-time temperature monitoring and light-proof facilities.
 2. Use sealed, light-proof, shockproof packaging (brown glass/stainless steel); mark obvious hazard signs (toxic, irritant, aquatic hazard) on the package.
 3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong bases and oxidizing agents in the transport vehicle; no mixed transport with other marine pollutants.
 4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials and full personal protective equipment; the driver and escort have professional hazardous chemical transport qualification certificates.
- **International Transport:** Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances; declare the nitrogen-containing heterocyclic and toxic 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 gastroenterology use; subject to national anti-gastrointestinal disease drug management regulations)
 - Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance, nitrogen-containing heterocyclic chemical)
 - Chinese Pharmacopoeia (2025 Edition)
 - GMP for Pharmaceutical Raw Materials (strict implementation standards)
 - Water Pollution Prevention and Control Law (strict restriction on environmental discharge)
- **International:**
 - GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 2 skin/eye irritation)
 - USP 45 / EP 10.0 (pharmacopoeial standards for clinical gastroenterology use)
 - REACH (EU) (registered; listed in SVHC Candidate List due to aquatic toxicity)
 - TSCA (US) (listed on the TSCA Inventory with environmental use restrictions)
 - IATA/IMDG/ADR (Class 6.1 toxic substances transport regulations)
 - FDA/EMA Approved (for acid-related gastrointestinal diseases treatment in the US and Europe)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; production and operation must comply with national gastroenterology drug management regulations and nitrogen-containing heterocyclic chemical management requirements.
- Occupational operation requires professional hazardous chemical and pharmaceutical production training and certification; operators must pass regular liver function, gastrointestinal, skin and ophthalmic 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.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (25 FEB 2026) unless the product formula or hazard information changes.



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- **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.
- **Additional Information:** For more technical/formulation data (only for clinical gastroenterology preparations), contact the supplier's technical department (+86-021-50350029 ext. 829) (only for licensed pharmaceutical enterprises).
- **Key Reminder:** This product is a **Class 6.1 toxic nitrogen-containing heterocyclic pharmaceutical raw material with gastrointestinal/hepatobiliary system damage risk, skin/eye irritation and aquatic toxicity**, a clinical gastroenterology therapy raw material for acid-related gastrointestinal diseases; 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 gastroenterology treatment guidelines and be administered under the supervision of gastroenterologists with strict monitoring of gastrointestinal symptoms and liver function indicators.



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