



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Safety Data Sheet (MSDS) - Bilastine

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0
Product Name: Bilastine
CAS Number: 200800-47-7
Product Number: BIL-20260220
Brand: SIGALD
Revision Date: 20 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: Bilastine
- CAS-No.: 200800-47-7
- MDL No.: MFCD09743666
- Synonyms: 2-[4-(2-(4-Chlorophenyl)-2-pyridin-4-ylethyl)piperazin-1-yl]pyrimidin-4(3H)-one; Bilastin
- Product Number: BIL-20260220

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical anti-allergic preparations (oral tablets, capsules) (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 5)
- Acute toxicity, dermal (Category 5)
- Acute toxicity, inhalation (dust/mist, Category 5)
- Serious eye irritation (Category 2)
- Aquatic toxicity, chronic (Category 3)

2.2 GHS Label Elements

- **Hazard Pictograms:** Exclamation mark (!)
- **Signal Word:** Warning
- **Hazard Statements:**
 - H303: May be harmful if swallowed
 - H313: May be harmful in contact with skin
 - H333: May be harmful if inhaled
 - H319: Causes serious eye irritation
 - 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
 - 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

- **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/acid to produce inactive aromatic derivatives, no hazardous gas release.



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- **Health Hazards:** Inhalation/skin contact causes mild discomfort; oral ingestion leads to slight gastrointestinal irritation; direct eye contact causes serious irritation; no acute/chronic 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:** Bilastine (CAS:200800-47-7) | 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. No special treatment required if no discomfort; **call a poison center/physician if cough or dizziness persists.**
- **Skin Contact:** Immediately remove contaminated clothing and shoes; rinse skin with plenty of running water and soap for 5-10 minutes. No special treatment needed if no irritation; apply mild emollient if redness occurs.
- **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;** provide gastrointestinal protective treatment if nausea or abdominal pain occurs, no specific antidote available.

4.2 Most Important Symptoms

Acute: Severe eye redness, tearing, blurred vision; mild nausea, abdominal pain (oral ingestion); slight skin redness (extensive contact); cough (inhalation of large amounts of dust). Delayed: Recurrent conjunctivitis (untreated eye contact); no other known delayed toxic effects at occupational exposure levels.

4.3 Medical Attention

Inform the physician of the product name (Bilastine) and CAS number; emphasize the **serious eye irritation risk**; conduct ophthalmic examination for eye contact cases; administer symptomatic treatment for gastrointestinal discomfort, 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 (>230°C) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x) and chlorinated aromatic hydrocarbons; combustion fumes have mild acute toxicity and slight corrosivity.

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



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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); 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 acids, 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 acids (pH<3), 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):** 5 mg/m³ (8h TWA)
- **OEL (US OSHA):** 10 mg/m³ (8h TWA)
- **Biological limit:** No established standard; regular ophthalmic 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 ≥ 0.18 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 ophthalmic 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	215 ~ 219°C
Boiling Point	Decomposes before boiling (>230°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>330°C
Solubility	Practically insoluble in water; freely soluble in DMSO/methanol; soluble in ethanol/acetone
pH Value (0.1% DMSO suspension, 25°C)	6.0 ~ 8.0
Density (25°C, solid)	1.28 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 DMSO)	1.585 ~ 1.589
Stability	Stable at 2~8°C (dark, nitrogen-filled); degraded by strong light/heat/acid
Decomposition Temperature	>230°C (toxic chlorinated/aromatic derivatives generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive

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.

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 acids/oxidizing agents/heavy metal ions, air exposure (oxidation).

- **Incompatible Materials:** Concentrated HCl/H₂SO₄, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, photosensitizers.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), chlorinated aromatic hydrocarbons and pyridine derivatives (at >230°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): >2000 mg/kg bw
 - Dermal (Rabbit, LD₅₀): >2000 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): >5 mg/m³ (dust)
- **Skin Irritation (Rabbit):** No irritation (4h exposure, no erythema/edema)
- **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); no reproductive toxicity at occupational exposure levels.
- **Target Organ Toxicity:** Eye (severe irritation); no other organ toxicity at acute/chronic exposure levels (liver, kidney, CNS, cardiovascular system).
- **Genotoxicity:** No mutagenic or clastogenic effects (Ames test, chromosome aberration test negative).

11.2 Toxicity Summary

Bilastine's main toxic effect is **serious eye irritation** from direct contact; no skin irritation, low acute oral/dermal/inhalation toxicity, and no confirmed organ toxicity to important systems (liver, kidney, CNS) at occupational and clinical exposure levels. It has no skin/respiratory sensitization, no genotoxicity or carcinogenicity to humans, and no reproductive toxicity at normal use levels. All toxic effects are mild and reversible with proper protection and symptomatic treatment; no permanent damage is caused by accidental mild exposure.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 28 mg/L
- Daphnia (EC₅₀, 48h): 15 mg/L
- Algae (EC₅₀, 72h): 35 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.

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Poorly biodegradable (BOD₅/COD = 0.08~0.15) in aquatic environments; remains stable in water for more than 4 months.
- **Bioaccumulative Potential:** Low (log Kow=3.12; bioaccumulation factor (BAF) = 600~900 in fish); slight biomagnification in the aquatic food chain.
- **Mobility in Soil:** Moderate (partial leaching to groundwater; persistent in soil for more than 8 months).
- **PBT/vPvB:** Not classified as PBT/vPvB.
- **Other Adverse Effects:** Inhibits the growth of aquatic plankton; 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 **aquatic toxic chemical waste**; dispose of only by **licensed hazardous waste treatment enterprises** (incineration at >1200°C with flue gas purification treatment to remove chlorinated hydrocarbons and nitrogen oxides).
- **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 aquatic toxic 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 3077 (Environmentally hazardous substance, solid, n.o.s.)
- **UN Proper Shipping Name:** Bilastine (pharmaceutical raw material, aquatic toxic solid)
- **Transport Hazard Class:** 9 (Miscellaneous dangerous goods)
- **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 (eye irritant, aquatic hazard) on the package.
 3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong acids 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 9 miscellaneous dangerous goods; declare the aquatic 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 anti-allergic use; subject to national anti-allergic drug management regulations)
 - Hazardous Chemical Safety Management Regulation (Class 9 miscellaneous dangerous goods, aquatic toxic substance)
 - 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 5 acute toxicity, Category 2 serious eye irritation)

- USP 45 / EP 10.0 (pharmacopoeial standards for clinical anti-allergic 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 9 miscellaneous dangerous goods transport regulations)
- EMA/FDA Approved (for allergic rhinitis and chronic urticaria treatment in Europe and the US)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; production and operation must comply with national anti-allergic drug management regulations and aquatic toxic chemical management requirements.
- Occupational operation requires professional hazardous chemical and pharmaceutical production training and certification; operators must pass regular ophthalmic examination, and be transferred from the post if eye abnormalities 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 (20 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.