

Safety Data Sheet (MSDS)

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

Naphazoline Hydrochloride

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

Product Identifiers

- Product Name: Naphazoline Hydrochloride
- Product Number: NH-20260218
- Brand: SIGALD
- CAS-No.: 550-99-2
- Synonyms: 2-(1-Naphthylmethyl)-2-imidazoline hydrochloride; Vasoconstrictor for ophthalmic/nasal preparations

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- 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 ophthalmic/nasal vasoconstrictor formulations; treatment of nasal congestion and ocular redness; pharmaceutical R&D reference reagent for cardiovascular pharmacology research.
- Uses Advised Against: Not for direct undiluted use; no oral administration without formulation; avoid use in cosmetic products without pharmaceutical grade formulation; do not use in pediatric preparations without professional dilution.

SECTION 2: Hazards Identification | Summary of Emergency Measures | White crystalline powder.

Harmful if swallowed or absorbed through mucous membranes. Causes serious eye irritation and mild skin irritation. May cause respiratory irritation if inhaled as dust. After inhalation: Move to fresh air and rest, seek medical advice if cough or chest tightness persists. In case of skin contact: Rinse with plenty of water and soap for 5 minutes. After eye contact: Rinse with plenty of water for at least 15 minutes and call a doctor immediately. After swallowing: Rinse mouth with water, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk. | | --- |

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2A); Specific target organ toxicity - single exposure (Cardiovascular system, Category 3)

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)



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>

- 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 (Cardiovascular system) 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 or oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.
- 2.4 Health Hazards Acute: Swallowing causes dizziness, tachycardia, hypertension, gastrointestinal discomfort; eye contact causes severe conjunctival redness, corneal irritation; skin contact leads to redness and itching; dust inhalation causes cough, nasal congestion. Chronic: Prolonged exposure may cause mild cardiovascular dysfunction (hypertension, arrhythmia), reversible with strict protective measures.
- 2.5 Environmental Hazards Low acute toxicity to aquatic organisms (96h LC₅₀ = 320 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**

表格

3.1 Main Components Naphazoline Hydrochloride (100%)

Formula	C ₁₄ H ₁₄ N ₂ ·HCl
Molecular Weight	246.74 g/mol
CAS-No.:	550-99-2



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>

3.1 Main Components Naphazoline Hydrochloride (100%)

EC-No.: 208-992-4

表格

Component	Classification	Concentration (w/w)
-----------	----------------	---------------------

Naphazoline Hydrochloride GHS Category 4/2/2A/3 100%

SECTION 4: First Aid Measures 4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air immediately, keep in a comfortable breathing position. Monitor respiratory and cardiovascular status; call a doctor if cough, chest tightness or palpitations persist.
- In Case of Skin Contact: Remove all contaminated clothing and shoes, rinse skin with plenty of running water and mild soap for at least 5 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **Immediate medical attention required.** 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 for professional treatment.
- If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor blood pressure and heart rate; call a POISON CENTER/doctor immediately for emergency treatment if dizziness, palpitations or hypertension occur.

4.2 Most Important Symptoms and Effects Acute: Dizziness, tachycardia, hypertension (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, nasal congestion (inhalation). Delayed: Mild cardiovascular dysfunction may occur 24-48 hours after excessive exposure; reversible with symptomatic treatment.

4.3 Indication of Immediate Medical Attention Severe swallowing exposure with cardiovascular symptoms, severe eye contact, prolonged respiratory irritation require immediate professional medical attention.

SECTION 5: Firefighting Measures 5.1 Extinguishing Media Suitable: Water spray, foam, carbon dioxide (CO₂), dry chemical powder. Unsuitable: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance Non-combustible; slight decomposition at high temperature (>300°C) produces low-toxic nitrogen-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 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. Monitor cardiovascular function of firefighters after exposure to decomposition fumes.

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 Sections For 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 cardiovascular 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 $\leq 25^{\circ}\text{C}$, relative humidity $\leq 60\%$. 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, cardiovascular toxic 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 cardiovascular drugs and pediatric pharmaceutical formulations.

SECTION 8: Exposure Controls/Personal Protection
8.1 Control Parameters No official national/international OEL; internal strict control limit: 0.03 mg/m^3 (8-hour TWA, dust) due to cardiovascular/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 $\leq 0.01 \text{ mg/m}^3$.

- 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 Information on Basic Physical and Chemical Properties
a) Physical State: Solid (crystalline powder)
b) Color: White to off-white
c) Odor: Practically odorless
d) Melting Point/Freezing Point: 254-260°C (decomposes)
e) Boiling Point: Not applicable (decomposes before boiling)
f) Flammability: Non-combustible
g) Flammability Limits: Not applicable
h) Flash Point: Not applicable
i) Autoignition Temperature: $> 450^{\circ}\text{C}$
j) Decomposition Temperature: $\geq 300^{\circ}\text{C}$ (mild decomposition, produces low-toxic fumes)
k) pH Value: 5.5-6.5 (1% aqueous solution, 25°C)
l) Viscosity: Not applicable (solid)
m) Solubility: Freely soluble in water, methanol, ethanol; slightly soluble in chloroform; insoluble in ether, benzene
n) Partition Coefficient (log P, n-octanol/water): 2.1 (25°C)
o) Vapor Pressure (25°C): < 0.0001 hPa
p) Density (25°C): 1.21-1.25 g/cm³ (bulk density)
q) Particle Size: 95% passing 100 mesh
r) Explosive Properties: Not explosives
s) Oxidizing Properties: None
t) Hygroscopy: Slightly hygroscopic, sensitive to light

SECTION 10: Stability and Reactivity
10.1 Chemical Stability: Stable under the recommended storage conditions ($\leq 25^{\circ}\text{C}$, dry, dark, sealed); stable under standard pharmaceutical processing temperature ($\leq 60^{\circ}\text{C}$).
10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment.
10.3 Conditions to Avoid: High temperature ($> 300^{\circ}\text{C}$), 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, cardiovascular toxic drugs.
10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic nitrogen-containing fumes (at high temperature complete combustion/decomposition); non-toxic Naphazoline derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information
11.1 Information on Toxicological Effects

- Acute Toxicity (**Vasoconstrictor pharmaceutical raw material**):
 - Oral (Rat, LD₅₀): 600 mg/kg (Harmful)
 - Dermal (Rabbit, LD₅₀): > 2000 mg/kg (Non-hazardous)
 - Inhalation (Rat, LC₅₀): 4.8 mg/m³ (4-hour exposure, Harmful)



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>

- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild redness and edema (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2A), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation, cough at low dust concentrations (≥ 0.25 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.
- Specific Target Organ Toxicity: **Cardiovascular system** is the main target organ; oral administration causes mild hypertension and tachycardia at excessive 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 LC₅₀): 320 mg/L
- Daphnia (48h EC₅₀): 300 mg/L
- Freshwater Algae (72h EC₅₀): 350 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD₅ /COD = 0.60); degraded by microorganisms in aquatic and soil environments within 15-20 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 2.1); no significant bioaccumulation in aquatic organisms and food chain due to rapid biodegradation.
- 12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (Koc = 180), 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 ($\geq 800^{\circ}\text{C}$) with flue gas treatment (to remove nitrogen-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).



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>

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811
14.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Naphazoline Hydrochloride)
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 vasoconstrictor/ophthalmic/nasal/irritant risk warning). Transport temperature $\leq 30^{\circ}\text{C}$; 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 cardiovascular drugs and pediatric pharmaceutical formulations. 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 ophthalmic/nasal 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 ophthalmic/nasal drugs); United States Pharmacopoeia (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 vasoconstrictor, ophthalmic and nasal pharmaceutical 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: **Vasoconstrictor pharmaceutical raw material for ophthalmic/nasal formulations, mild cardiovascular toxicity, low environmental toxicity.**



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>

- Revision Date: 18 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety regulations.

