



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) - Isoniazid

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0 **Product Name:** Isoniazid **CAS Number:** 54-85-3 **Product Number:** IN-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: Isoniazid
- CAS-No.: 54-85-3
- MDL No.: MFCD00007505
- Synonyms: Isonicotinic acid hydrazide; INH; 4-Pyridinecarboxylic acid hydrazide
- Product Number: IN-20260222

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical anti-tuberculosis preparations (oral tablets, capsules, syrups, injections) (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 (central nervous system, liver, Category 2)
- Specific target organ toxicity - repeated exposure (liver, 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
 - H371: May cause damage to organs (CNS, liver) through single exposure
 - H372: May cause damage to organs (liver) 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

- **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 pyridine derivatives, no hazardous gas release.
- **Health Hazards:** Inhalation/skin contact/swallowing causes skin/eye irritation, gastrointestinal discomfort and mild neurological reactions; single high-dose exposure may cause liver and central nervous system damage; long-term exposure leads to cumulative liver function damage; oral ingestion has moderate acute toxicity.
- **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:** Isoniazid (CAS:54-85-3) | 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 breathing is difficult, give oxygen; **call a poison center/physician if discomfort (dizziness, cough) persists.** Monitor for CNS and liver function 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 emollient if redness/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;** continue to monitor eye redness, swelling and vision until symptoms disappear.
- **Swallowed:** Do not induce vomiting; rinse mouth with water. **Call a poison center/doctor at once;** perform gastric lavage under medical supervision if necessary; check liver function indicators (ALT/AST) and provide liver protective and neurological symptomatic treatment.

4.2 Most Important Symptoms

Acute: Dizziness, headache, nausea, vomiting, abdominal pain, skin redness/erythema, eye redness/tearing and blurred vision; severe oral ingestion causes liver function abnormality, convulsions and ataxia. Delayed: Cumulative liver function damage, persistent elevation of transaminase, chronic skin irritation, recurrent conjunctivitis (long-term exposure); rare peripheral neuritis with prolonged contact.

4.3 Medical Attention

Inform the physician of the product name (Isoniazid) and CAS number; emphasize the **liver/CNS damage and local irritation risk;** conduct liver function, blood routine and neurological examinations regularly for at least 1 month after exposure; administer liver protective drugs and symptomatic treatment for abnormal indicators; pyridoxine (vitamin B6) can be used to alleviate neurological side effects if needed.

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 (>200°C) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x), pyridine and hydrazine derivatives; combustion fumes have mild acute toxicity.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full 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 full level C PPE (nitrile rubber gloves, chemical safety goggles, full face shield, N95 respirator, impermeable protective clothing); avoid any 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; 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 dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information; 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 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.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation; take a shower if the body is contaminated.
- Avoid contact with strong acids, 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 acids (pH<3), strong bases (pH>9), oxidizing agents (H₂O₂, KMnO₄), heavy metal salts (Fe³⁺, Cu²⁺), hydrazine reactants, 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):** 3 mg/m³ (8h TWA)
- **OEL (US OSHA):** 5 mg/m³ (8h TWA)
- Biological limit: Monitor liver function indicators (ALT/AST) and pyridoxine levels for operators; no specific biological exposure limit established.

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 ≥0.18mm) + impermeable 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/shower 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 (quarterly) including liver function, neurological and ophthalmic examination; supplementary pyridoxine (vitamin B6) for long-term operators if needed.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless or slight faint odor
Melting Point	170 ~ 173°C
Boiling Point	Decomposes before boiling (>200°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>300°C
Solubility	Freely soluble in water; soluble in ethanol; slightly soluble in ether/benzene
pH Value (1% aqueous solution, 25°C)	5.0 ~ 6.5
Density (25°C, solid)	1.24 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, 5% aqueous solution)	1.468 ~ 1.472
Stability	Stable at 2~8°C (dark, nitrogen-filled); degraded by strong

Property	Value
Decomposition Temperature	light/heat/alkali >200°C (pyridine/hydrazine derivatives generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Viscosity	Not applicable (solid)

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 and injectable 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/alkalis/oxidizing agents/heavy metal ions, air exposure (oxidation/hydrolysis).
- **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, potassium permanganate, iron(III) chloride, copper sulfate, photosensitizers, hydrazine-based compounds.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), pyridine, hydrazine and isonicotinic acid derivatives (at >200°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): 1480 mg/kg bw
 - Dermal (Rabbit, LD₅₀): >2000 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 4.2 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.
- **Target Organ Toxicity:** Liver (hepatocellular damage), central nervous system (dizziness, convulsions, peripheral neuritis), skin/eye (local irritation); no other organ toxicity at occupational exposure levels.
- **Genotoxicity:** No mutagenic or clastogenic effects (Ames test, chromosome aberration test negative).

11.2 Toxicity Summary

Isoniazid's main toxic effects are **severe eye irritation and moderate skin irritation** from direct contact, **gastrointestinal and central nervous system reactions** from oral ingestion/inhalation, and **cumulative liver function damage** from long-term exposure; the toxic effects are mild and reversible with symptomatic and liver protective 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 peripheral neuritis can be alleviated by pyridoxine supplementation.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 32 mg/L
- Daphnia (EC₅₀, 48h): 18 mg/L
- Algae (EC₅₀, 72h): 40 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 = 0.1~0.2) in aquatic environments; remains stable in water for more than 4 months.
- **Bioaccumulative Potential:** Low (log Kow=-0.67; bioaccumulation factor (BAF) = 50~100 in fish); no obvious biomagnification in the aquatic food chain.
- **Mobility in Soil:** Moderate (partial leaching to groundwater; persistent in soil for more than 6 months).
- **PBT/vPvB:** Not classified as PBT/vPvB.
- **Other Adverse Effects:** Inhibits the growth and reproduction of aquatic microorganisms and 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 **toxic 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 pyridine 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 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 2811 (Toxic solid, organic, n.o.s.)
- **UN Proper Shipping Name:** Isoniazid (toxic pharmaceutical raw material, solid)
- **Transport Hazard Class:** 6.1 (Toxic substances, Category 4)
- **Packaging Group:** III (Minor danger)
- **Marine Pollutant:** No
- **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) on the package.

3. Load/unload gently; avoid package damage and collision; store separately from food, feed, strong acids/alkalis, oxidizing agents and other drugs in the transport vehicle; no mixed transport with other hazardous goods.
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 and first-aid training.
- **International Transport:** Comply with IATA/IMDG/ADR regulations for Class 6.1 toxic substances; apply for international hazardous chemical transport approval in advance; declare the toxic characteristics to the customs and transport department.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**
 - Pharmaceutical Administration Law (pharmaceutical raw material for clinical anti-tuberculosis use; subject to national antimicrobial drug management regulations)
 - Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance)
 - Chinese Pharmacopoeia (2025 Edition)
 - GMP for Pharmaceutical Raw Materials (strict implementation standards)
 - Occupational Disease Prevention and Control Law (special occupational protection for operators)
 - Anti-Tuberculosis Law (core first-line anti-TB drug, subject to national tuberculosis control regulations)
- **International:**
 - GHS Rev.9 (hazard classification: Category 4 acute toxicity, Category 2 skin/eye irritation)
 - USP 45 / EP 10.0 (pharmacopoeial standards for clinical anti-tuberculosis use)
 - REACH (EU) (registered; not listed in SVHC Candidate List)
 - TSCA (US) (listed on the TSCA Inventory with normal use restrictions)
 - IATA/IMDG/ADR (Class 6.1 toxic substances transport regulations)
 - WHO Essential Medicines List (core anti-tuberculosis drug, subject to WHO anti-TB treatment guidelines)

15.2 Other Requirements

- Production/sale/use limited to **licensed pharmaceutical enterprises** with GMP certification; production and operation must comply with national anti-tuberculosis drug management regulations and antimicrobial drug use norms.
- Occupational operation requires professional hazardous chemical and pharmaceutical production training and certification; operators must pass regular occupational health checkups (focus on liver function, neurological and ophthalmic systems), and be transferred from the post if abnormal indicators are found.
- The whole process (production, storage, transport, use, waste disposal) is subject to supervision by drug regulatory, emergency management, environmental protection and health 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 (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.



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- **Additional Information:** For more technical/formulation data (only for clinical anti-tuberculosis preparations), contact the supplier's technical department (+86-021-50350029 ext. 820) (only for licensed pharmaceutical enterprises).
- **Key Reminder:** This product is a **toxic pharmaceutical raw material with liver/CNS damage risk and aquatic toxicity**; any illegal production/sale/use/transport/disposal will be subject to legal liability in accordance with national and international laws. It is a core WHO essential anti-tuberculosis drug, and its clinical use must follow standardized combination therapy guidelines.

